Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. AND TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-663 (VAC) (SRF) CONSOLIDATED

[PROPOSED] STIPULATED PROTECTIVE ORDER

Pursuant to Federal Rule of Civil Procedure 26(c), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") and Defendants Taro Pharmaceutical Industries Ltd. ("TPIL") and Taro Pharmaceuticals, Inc. ("TPI") (collectively, "Taro" or "Defendants") request that the following Stipulated Protective Order ("Protective Order" or "Order") be entered in the above-captioned cases (the "Proceedings") to govern the exchange of discovery materials by the parties and third parties, the use or exhibition of documents and things during discovery, and testimony containing trade secrets, confidential or proprietary research, development, technical, financial, strategic, customer, or commercial information, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G), and personal health information protected under state or federal privacy laws, or other applicable personal data protection laws. Plaintiff and Defendants (all collectively, "the Parties") and this Court agree that the disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the Parties and third parties. Therefore, good cause exists for entry of this Protective Order to preserve the confidentiality of certain documents and

information, to outline procedures and reasonable restrictions on the disclosure of sensitive materials, and to permit discovery to proceed without delay.

Accordingly, the Court hereby enters the following Protective Order, which shall control the disclosure, dissemination, and use of information in these Proceedings:

I. DESIGNATION OF MATERIAL AS "CONFIDENTIAL" OR "HIGHLY CONFIDENTIAL"

1. This Protective Order applies to any document, or portion thereof, any type of information, including electronically stored information and any form of discovery contemplated under Rules 26 through 36 of the Federal Rules of Civil Procedure that, in the good-faith opinion of the party providing such material (the "Producing Party" or "Designating Party"), contains any trade secret or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information of the Producing Party, or a nonparty if such documents and information are within the possession, custody or control of the Producing Party. The party receiving such information is herein referred to as the "Receiving Party" or "Non-Designating Party." This Protective Order describes the information protected under its terms and the use and disclosure of such protected information.

2. The designation of material as "Confidential" as used in this Protective Order means information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c), [Plaintiff's proposal includes the following underlined language] including but not limited to any documents and things relating to (i) the names, or other information tending to reveal the identities, of a party's suppliers, present or prospective customers, or distributors or the personal information of a party's employees; (ii) information relating to pending patent applications; (iii) commercial information, including, without limitation, strategic plans, marketing and financial information

concerning a party's current products, processes and/or business relationships or potential future products, processes and/or business relationships; (iv) information constituting product specifications, formulations, and/or regarding the manufacture of the party's products; (v) technical notebooks and technical reports of a party, including product and manufacturing specifications, schematic diagrams, technical reference manuals, operations manuals, or other similar information; (vi) confidential marketing plans, market research and business strategy, including research regarding competitors; (vii) information the Designating Party believes is a proprietary trade secret; (viii) personal information and/or identities of physicians and patients; (ix) all information relating to a party's research and development efforts; (x) all New Drug Applications ("NDAs"), Abbreviated New Drug Applications ("ANDAs"), or Drug Master Files ("DMFs"); and (xi) physical samples of any products described in an NDA (except for samples of publically available drug products) or ANDA. Identification of types of documents in this Paragraph shall not be an admission by either of the Parties that such documents are relevant or admissible in these Proceedings. Confidential information may be contained in discovery information or materials produced or obtained in these Proceedings by or through any means and by or through any person or entity. The Confidential information contained therein and all copies, recordings, abstracts, excerpts, analyses, or other writings that contain, reveal, or otherwise disclose such Confidential information shall also be deemed Confidential information.

3. The designation of material as "Highly Confidential" by the Producing Party constitutes its reasonable, good-faith representation that the material disclosed is so sensitive and confidential that the disclosure, whether separately or in conjunction with other information being disclosed, is believed in good faith by the disclosing party to have the potential for causing serious competitive harm or giving a competitive advantage to others, and that access to such

information should be more limited. Information that may be designated "Highly Confidential" means information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c) that satisfies the requirements of Paragraph 2 and which comprises or contains particularly sensitive information of the Parties or third parties and their affiliates, [Plaintiff's proposal includes the following underlined language] including but not limited to current or future financial documents (for example, P&L statements), business strategy, projected future sales, pricing, customer/vendor agreements, revenue, cost, or profit information for its products, information that any party is required to maintain in confidence under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and any other information a Producing Party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the Receiving Party. Identification of types of documents in this Paragraph shall not be an admission by either of the Parties that such documents are relevant or admissible in these Proceedings. The Producing Party may designate discrete pages or volumes of such information, on a document-by-document basis, as "Highly Confidential." This provision does not permit a Producing Party to designate entire categories of materials as "Highly Confidential" without making an individual assessment of sensitivity on a document-by-document basis. [Plaintiff's proposal includes the following underlined language] Nor does this provision permit the designation as "Highly Confidential" any of the following materials concerning the subject matter of these Proceedings: technical or regulatory information relating to, referring to, or concerning NDA No. 207154 and the products described therein, or ANDA No. 210191 and the products described therein; including, but not limited to, the NDA or ANDA, any correspondence or other communication to or from FDA regarding the relevant application, and DMFs associated with or referenced in the NDA or

ANDA. Information designated as "Highly Confidential" may only be disclosed to Qualified Persons identified in Paragraph 15.

4. Any party or third party may designate as "Confidential" or "Highly Confidential" all or any part of any discovery or other materials produced or served in these Proceedings, or filed with the Court, including without limitation, documents and things, pleadings, motions, briefs, contentions, expert reports, interrogatory answers, deposition testimony, and responses to requests for admission, which contain sensitive proprietary, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26(c)(1)(G), as set forth in Paragraphs 2 and 3 above.

5. A party or third party shall designate a document or thing as "Confidential" or "Highly Confidential" when it is produced to the party seeking discovery by marking it prominently on its face with the legend in substantially the following form: "CONFIDENTIAL," "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER," "HIGHLY CONFIDENTIAL," or "HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER," as appropriate. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. If an entire multi-page document is to be treated as Confidential or Highly Confidential information, each page of such document should be marked. In addition, each page of each document and each thing produced pursuant to discovery in these Proceedings shall bear a unique identifying number.

6. Notwithstanding such designation, Confidential or Highly Confidential information does not include information obtained independently of these Proceedings as to which no obligation of confidentiality applies. Accordingly, nothing in this Order shall prevent

any person, including a Qualified Person, from making use of any information that is designated as Confidential or Highly Confidential information if such information:

a. is determined by agreement of the Parties or order of the Court to be public information,

b. was lawfully in his or her possession prior to receiving the information or document under the provisions of this Order,

c. was, is, or becomes available to the public through no fault of a Receiving Party,

d. is disclosed by a third party who is not subject to any confidentiality obligations at the time of the disclosure, or

e. is discovered independently by the Receiving Party by means that do not constitute a violation of this Order.

7. Nothing in this Order shall prevent a party or third party from redacting from documents or things, which otherwise contain relevant discoverable information, any Confidential or Highly Confidential information that is irrelevant to these Proceedings or otherwise not discoverable, such as information relating to non-accused products, including products in development, pursuant to Federal Rule of Civil Procedure 26(b).

8. Prior to production, a party or third party may redact from all documents, e-mails, and personal electronic files all personal information, including the following: home address, home and cell phone numbers, pager numbers, names of spouses and children, credit card information, benefits information, compensation information, and personal information found in employee files.

9. Unless otherwise agreed by the Parties, deposition transcripts taken in connection with these Proceedings will be temporarily designated and treated as Highly Confidential information for up to fourteen (14) calendar days after both Parties have received a final transcript of the deposition, in order to give the Parties or third parties the opportunity to properly designate any Confidential or Highly Confidential information in the transcript. A party may designate a deposition transcript as Confidential or Highly Confidential during the deposition at which such information was disclosed, or within those fourteen (14) calendar days after receipt of the final transcript, the Parties and/or third parties may designate any or all portions of the transcript as Confidential or Highly Confidential information in accordance with this Protective Order. If a deposition transcript or deposition exhibits contain Confidential information, the deposition transcript will be marked on its first page with the legend "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." If the deposition transcript or deposition exhibits contain Highly Confidential information, the deposition transcript will be marked on its first page with the legend "HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." A deponent may review the transcript of his or her deposition at any time. Nothing in this Paragraph shall prevent a party from showing to its own employees, officers, directors, or agents transcripts from depositions taken of its own fact witnesses, unless such witness is a person identified in Paragraph 14(b), or their secretarial, clerical, paralegal, and other supporting personnel, and the transcript contains Confidential information of the other party group.

10. Any material provided for inspection, as opposed to documents produced outright, in these Proceedings is to be treated by the inspecting/receiving party as Highly Confidential information pending the copying and delivery of any copies of the same by the Producing Party.

After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel or independent consultants or experts eligible under Paragraph 14(a) or 14(c) below.

11. [Plaintiff's proposal: For any documents produced before the entry of this Order and marked under District of Delaware Local Rule 26.2, the Receiving Party will treat them as Confidential information, unless the Producing Party subsequently designates them otherwise.] [Defendants' proposal: For all documents produced before the entry of this Order pursuant to District of Delaware Local Rule 26.2, the Receiving Party shall treat them as Highly Confidential information, unless the Producing Party subsequently designates them otherwise.]

12. Documents and things produced without a legend designating the material Confidential or Highly Confidential information shall not be subject to this Protective Order, unless otherwise agreed to by the Parties or ordered by the Court.

II. USE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION

13. Confidential and Highly Confidential information, including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be held in confidence by the Receiving Party, shall be used only by persons permitted access to the information under this Protective Order, and shall not be used for any purpose other than in connection with these Proceedings, any appeal therefrom, and remands thereto, including without limitation for any research, development, patent prosecution, commercial, marketing, regulatory, or other competitive purposes. Subject to Paragraphs 14 and 15 below, all persons receiving Confidential or Highly Confidential information are prohibited from using or disclosing such information in connection with practice before or communication with the

United States Patent and Trademark Office ("USPTO"), the United States Food and Drug Administration, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction. Nothing contained in this Order shall preclude any party from using its own Confidential or Highly Confidential information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Order shall restrict any party's counsel from rendering advice to its clients with respect to these Proceedings and, in the course thereof, relying upon Confidential or Highly Confidential information, provided that in rendering such advice counsel shall not disclose any other party's Confidential or Highly Confidential information other than in a manner provided for in this Order.

III. ACCESS TO CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION

14. Confidential information, and any material containing such information, may be made available to, and inspected by, only the following "Qualified Persons":

(a) Outside counsel of record of the Receiving Party; and their partners, associates, paralegals, secretaries, and other supporting personnel who have actually received or reviewed such Confidential information (collectively, "Outside Counsel").

Outside Counsel who receives or reviews Confidential information shall not, during the pendency of the Proceedings, and for a period of eighteen (18) months after final termination of the Proceedings, including any appeals, participate in (1) the preparation or prosecution of any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient; (2) any amendment or addition of claims in the patent-in-suit in any post-grant proceeding (including *inter partes* review) before the USPTO on any patent-in-suit or any patent issued from any application that (a) is a continuation, continuation-in-part, division, or reissue application of the patent-in-suit; or (b) claims the priority of U.S. Provisional

Application No. 61/728,403 or 61/770,768 or is a divisional of U.S. Application No. 14/082,955; or (3) the preparation or submission of any Citizen Petition concerning any dapsone 7.5% gel product. For clarity, "Outside Counsel," as used herein, do not include other individuals employed by the same law firm as outside counsel of record of the Receiving Party, who have not actually received or reviewed the Confidential information. In addition, this provision does not preclude Outside Counsel from receiving or reviewing Confidential information if they manage others who prepare or prosecute any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient, so long as the Outside Counsel does not participate in such preparation or prosecution, or rely on Confidential information in advising others to prepare or prosecute any such patent application. Outside Counsel who receives or reviews Confidential information may participate in post-grant proceedings (including *inter partes* proceedings, post-grant review, covered business method review, or *ex parte* reexamination) before the USPTO, or corresponding proceedings before any foreign patent authority, with the exception that Outside Counsel who receives or reviews Confidential information shall not participate, directly or indirectly, including by advising others, in the drafting or amendment of claims concerning any patent that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient;

(b) Allergan and Taro may each designate up to two (2) in-house counsel [Defendants' proposal includes the following underlined language] or IP Personnel employed by the party, or by the party's subsidiary, parent, and/or affiliate, with responsibilities for managing this litigation, and their secretarial, clerical, paralegal, and other supporting personnel, provided that the designated in-house counsel are not directly responsible for competitive decision-

making. "Competitive decision-making," as used herein, does not include (a) legal decision-making or advising responsibilities relating to topical products containing dapsone, including, for example, negotiating or executing agreements to settle litigation including responsibilities related to any financial terms of such agreements, advising about product launch dates or other product plans, or (b) interfacing with, for the purposes of carrying out responsibilities as an attorney, individuals responsible for competitive business decisions concerning topical products containing dapsone.

Designated in-house counsel who receives or reviews Confidential information shall not, during the pendency of the Proceedings, and for a period of eighteen (18) months after final termination of the Proceedings, including any appeals, participate in (1) the preparation or prosecution of any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient; (2) any amendment or addition of claims in the patent-in-suit in any post-grant proceeding (including *inter partes* review) before the USPTO on any patent-in-suit or any patent issued from any application that (a) is a continuation, continuation-in-part, division, or reissue application of the patent-in-suit; or (b) claims the priority of U.S. Provisional Application No. 61/728,403 or 61/770,768 or is a divisional of U.S. Application No. 14/082,955; or (3) the preparation or submission of any Citizen Petition concerning any dapsone 7.5% gel product. For clarity, this provision does not preclude the designated in-house counsel from receiving or reviewing Confidential information if they manage others who prepare or prosecute any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient, so long as the in-house counsel does not participate in such preparation or

prosecution, or rely on Confidential information in advising others to prepare or prosecute any such patent application. In-house counsel who receives or reviews Confidential information may participate in post-grant proceedings (including *inter partes* proceedings, post-grant review, covered business method review, or *ex parte* reexamination) before the USPTO, or corresponding proceedings before any foreign patent authority, with the exception that in-house counsel who receives or reviews Confidential information shall not participate, directly or indirectly, including by advising others, in the drafting or amendment of claims concerning any patent that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient.

As of the date of this Order, the designated in-house counsel are:

- For Allergan: (1) Brian Anderson; and (2) Shenade Walker.
- For Taro: (1) Craig Kuchii; and (2) TBD.

Allergan and Taro shall each have the right to add new persons or substitute new persons for in-house counsel designated under this Paragraph to receive Confidential information, provided that at any time no more than two designated people from each side shall have access to Confidential information pursuant to this Protective Order;

(c) Independent experts or consultants and their staff retained to assist the Receiving Party in the conduct of these Proceedings, provided such experts and consultants have complied with Paragraphs 18 and 19 herein;

(d) Witnesses or deponents who (1) are indicated on the face of the document or thing containing Confidential information as an author or recipient of the document or thing; (2) who have been identified, through discovery (including document production, written discovery, or deposition testimony) or some other basis for providing a reasonable belief, as

having authored or received the document or thing, or similar or related documents or things from the same general time period, even if the individual is not identified as an actual author or recipient on the face of the document or thing at issue; or (3) who are (i) current employees of the Producing Party or who are (ii) former employees of the Producing Party who were employees of the Producing Party or its predecessor in interest, as of the date of the document or thing;

(e) The Court and personnel employed by the Court;

(f) Court reporters and videographers;

(g) Photocopy services;

(h) Professional translators who are retained by counsel for the Parties for the purposes of these Proceedings;

(i) Graphics or design consultants retained to prepare demonstrative or other exhibits for use in these Proceedings;

(j) Non-technical jury or trial consultants and persons employed or retained by them;

(k) Document imaging and database services and consultants retained to set up, maintain, and/or operate litigation databases; and

(l) Others as to whom the Designating Party has given written consent.

15. Highly Confidential information, and any material containing such information, may be made available to, and inspected by, only the Qualified Persons identified in Paragraphs 14(a) and 14(c)–(*l*). For the avoidance of doubt, Highly Confidential information will not be made available to or inspected by in-house counsel or in-house IP personnel for the parties.

16. Only Qualified Persons, the deponent, and his or her attorney (if any), shall be allowed to attend any portion of a deposition in which Confidential or Highly Confidential information is used or elicited from the deponent. Counsel for the Designating Party may also request that all persons other than the witness, the court reporter and videographer, Qualified Persons specified in Paragraph 15, and counsel for the witness (if a third party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Highly Confidential by the Designating Party. Counsel for the Designating Party may also request that all persons other than the witness, the court reporter and videographer, Qualified Persons specified in Paragraph 14, and counsel for the witness (if a third party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Confidential by the Designating Party. The failure of individuals other than those specified in the previous two sentences to leave the deposition room during any portion of the deposition which inquires into matters deemed Confidential or Highly Confidential by the Designating Party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question(s) posed concerning such matters.

17. This Order shall not limit a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential or Highly Confidential information under the terms of this Order, so long as such examination concerns Confidential or Highly Confidential information that the witness authored, received, or previously had access to or knowledge of, the witness was involved in the subject matter described therein, or the witness is a present or former employee of the party that produced the information, document, or thing, as demonstrated by the information itself, by foundation testimony during a deposition, hearing or trial, or if the Producing Party consents to such disclosure. This Order shall not prevent counsel

from examining a witness in a good-faith effort to determine whether he or she authored, received, was involved in the subject matter described therein, or previously had access to or knowledge of Confidential or Highly Confidential information.

18. Before disclosing another party's Confidential or Highly Confidential information to persons or entities described in Paragraph 14(c), the party shall first obtain a signed Certification in the form of the annexed Exhibit A. The Certification shall be signed by the independent consultant or expert retained by the party, and a single Certification by the independent consultant or expert shall be sufficient to cover all employees of the independent consultant or expert. Counsel retaining the person(s) described in Paragraph 14(c) shall retain the original of each such signed Certification.

19. Before disclosing another party's Confidential or Highly Confidential information to any outside consultant or expert described in Paragraph 14(c), the party shall first provide to the Producing Party (a) a signed copy of the Certification found in Exhibit A of this Order, (b) a current resume (*curriculum vitae*) of the consultant or expert including a list of publications, and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the Producing Party has received the requisite documents and consultant/expert information, the Producing Party shall then have seven (7) calendar days to provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made, (a) there shall be no disclosure of the Confidential or Highly Confidential information to the consultant or expert, except by further order of the Court or by agreement by the Parties, (b) the Parties agree to promptly meet and confer in good faith regarding the basis for (and resolution of) the objection, and (c) if the Parties

cannot reach an agreement, the party objecting to the disclosure of information to the consultant/expert may pursue the issue via the Court's established discovery dispute procedures within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this Paragraph, the objecting party shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or to timely file a motion with the Court will act as a waiver of the objection, and the consultant or expert will become a Qualified Person.

IV. INADVERTENT PRODUCTION OF INCORRECTLY DESIGNATED MATERIAL

20. Inadvertent production of any document, thing, or information without a designation of Confidential or Highly Confidential information will not be deemed to waive a later claim as to its confidential nature, or stop the Producing Party from designating said document or information as Confidential or Highly Confidential information at a later date.

21. Any Producing Party may change a designation to Confidential or Highly Confidential (or withdraw a designation) regarding any material that it has produced by notifying counsel for each party in writing. Upon receipt of such notice, the Non-Designating Party shall: (i) not make any further disclosure or communication of such newly designated material except as provided for in this Order; (ii) take reasonable steps to notify any persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation under this Order; (iii) for material newly designated as Highly Confidential, promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not Qualified Persons under Paragraph 15; and (iv) for material newly designated as Confidential, promptly retrieve or have destroyed all copies and

transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not Qualified Persons under Paragraph 14. Properly marked documents, reflecting the new designation, shall be promptly provided by the Producing Party.

V. CHALLENGING A "CONFIDENTIAL" OR "HIGHLY CONFIDENTIAL" DESIGNATION

22. A party receiving documents or things shall not be obligated to challenge the propriety of a Confidential or Highly Confidential information designation (or re-designation) at the time the document or thing is produced, and a failure to do so shall not preclude a subsequent challenge thereto. If a Receiving Party disagrees at any time with a Confidential or Highly Confidential information designation made by another party or a third party, the following procedure shall be used:

a. The party seeking to change the designation of another party's documents, things, or information shall provide the Producing Party written notice specifying the documents, things, or information for which a change in designation is sought, and the reasons for the request. The Producing Party shall have seven (7) calendar days after receipt of the written notice within which to object in writing to the change in designation or removal of protection afforded by this Order and to specify why protection under this Order is appropriate.

b. If the Producing Party objects in writing within seven (7) calendar days of receiving such a written notice, both Parties shall meet and confer in an attempt to resolve the dispute without involvement of the Court.

c. If the Parties and/or third parties cannot reach agreement concerning the change in designation, the party seeking the removal of protection for the Confidential or Highly

Confidential information may pursue the issue via the Court's established discovery dispute procedures.

d. The Parties shall continue to treat the document(s) or thing(s) at issue as Confidential or Highly Confidential information (according to the original designation(s)) until the dispute is resolved by Order of this Court, or by agreement of the Parties and/or third parties.

e. On any motions arising out of the designation of any material as Confidential or Highly Confidential information under this Order, the burden of justifying the designation shall lie with the Producing Party.

VI. INADVERTENT USE OF CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION

23. If Confidential or Highly Confidential information is used inadvertently during the course of the Proceedings (including at depositions) inconsistent with or in contravention of other provisions of this Order, the information shall not lose its confidential status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its confidentiality after such inadvertent use. If Confidential or Highly Confidential information is inadvertently disclosed to a deposition witness, and the witness has testified that he or she has knowledge concerning that information, the witness may be examined and cross-examined with respect to the document or information disclosed for the remainder of the deposition.

24. If Confidential or Highly Confidential information is disclosed to any person other than in the manner authorized by this Order, the party responsible for the disclosure shall within five (5) calendar days of learning of such disclosure inform the Producing Party of all pertinent facts relating to such disclosure. As soon as possible thereafter, the Parties shall also use reasonable efforts to obtain the prompt return of any such Confidential or Highly Confidential information, and obtain a signed Certification attached hereto as Exhibit A from

each unauthorized person or party who received Confidential or Highly Confidential information. The requirements set forth in this Paragraph shall not prevent the Producing Party from requesting that the party responsible for the inadvertent disclosure take additional remedial steps and/or applying to the Court for additional relief.

VII. INADVERTENT PRODUCTION OR USE OF PRIVILEGED INFORMATION

25. If information subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information from discovery is inadvertently produced in any way, such production shall not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the Producing Party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Federal Rule of Civil Procedure 26(b)(5)(B) and/or Federal Rule of Evidence 502.

26. If a written claim of inadvertent production of privileged information is made by a Producing Party to a Receiving Party, the Receiving Party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested document physically at the deposition must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 26(a), destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced information or documents possessed by the Receiving Party and by those persons to whom the Receiving Party may have disclosed such information.

27. Recognizing the need for the Parties to prepare for their cases based on the discovery that is produced, if any information, document, or thing is used openly in the case, *e.g.*, at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production based on privilege, must be made within two (2) weeks after such use.

28. Nothing herein shall prevent the Receiving Party from challenging the propriety of the attorney-client privilege, work product immunity, or other privilege designation, or from presenting the information to the Court under seal for a determination of the privilege claim through a written challenge to the Court. The Receiving Party must preserve the confidentiality of the document or information until the claim is resolved.

VIII. INADVERTENT PRODUCTION OF ELECTRONICALLY STORED INFORMATION

29. If electronically stored information ("ESI") is inadvertently produced as the result of an error in the ESI production process, including but not limited to, predictive coding errors, optical character recognition ("OCR") errors, or errors in the application of search terms to ESI databases, such production shall not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the Producing Party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Federal Rule of Civil Procedure 26(b)(5)(B) and/or Federal Rule of Evidence 502.

30. If a written claim of inadvertent production of ESI is made by a Producing Party to a Receiving Party, the Receiving Party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed ESI; if the inadvertent disclosure is

discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested ESI physically at the deposition must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 30(a), destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced ESI possessed by the Receiving Party and by those persons to whom the Receiving Party may have disclosed such information.

31. Recognizing the need for the Parties to prepare for their cases based on the discovery that is produced, if any ESI is used openly in the case, *e.g.*, at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production of such ESI must be made within two (2) weeks after such use.

32. Nothing herein shall prevent the Receiving Party from challenging the propriety of the claim of inadvertent production of ESI. The Receiving Party must preserve the confidentiality of the document or information until the claim is resolved.

IX. PRODUCTION OR DISCLOSURE OF A THIRD PARTY'S INFORMATION

33. Any subpoena or other notice to a third party requesting production of documents shall include a copy of this Protective Order.

34. If a third party produces documents pursuant to a subpoena or other request issued by one of the Parties (or by Court order) and if the third party has not requested its documents be treated as Confidential or Highly Confidential, then it shall be presumed that the documents produced contain information for which the third party has determined require no designation under this Protective Order. The third party's documents and things shall be handled by all Parties to these Proceedings according to the appropriate designations under this Protective Order. The party issuing the subpoena or other request for documents or things to the third party

shall provide any non-requesting party an opportunity to review and make copies of any documents produced in response to that subpoena or request.

35. A party in these Proceedings may temporarily withhold production of otherwise discoverable information sought in a discovery request (*e.g.*, interrogatory, request for production, or request for admission) if the party is under an obligation to a third party not to disclose such information (*e.g.*, by prior agreement of confidentiality). In such an event (except for information subject to another protective order or confidentiality order by another court), the Producing Party shall:

a. timely serve a written objection to the production of the requested information on the basis of its obligation to a third party not to disclose such information;

b. promptly provide to the third party whose confidentiality interests are implicated (i) notice of the pending request to disclose the information, and (ii) a copy of this Protective Order; and

c. if the third party does not agree to disclosure of its information, then the party requesting the documents or things from the third party may (i) serve a subpoena on the third party, if the requesting party has not already done so, or (ii) file a motion to compel production of the requested documents against a party and/or third party in the appropriate Court.

36. Any party to these Proceedings that receives a subpoena or other request from a third party that seeks the disclosure/production of Confidential or Highly Confidential information already disclosed in these Proceedings that the party did not itself produce shall give prompt telephonic and written notice to that original Producing Party of such subpoena or other request, but in no event more than seven (7) calendar days after actual receipt of the subpoena or other request. If the original Producing Party opposes disclosure of its documents called for by

the subpoena or other request, then the party served with the subpoena shall not disclose the pertinent information until a Court has resolved the issue. Absent a Court order, production or disclosure of another party's information shall not be made until the original Producing Party has agreed to such production to a third party. The original Producing Party shall bear the burden to oppose, if it deems appropriate, the subpoena or other request on the grounds of confidentiality. This Paragraph shall not apply to disclosure of information pursuant to a third party's subpoena or request for Confidential or Highly Confidential information, if the party receiving the subpoena or request itself produced the documents or things called for by the subpoena or request, i.e., this Paragraph shall not apply to the disclosure of a party's own documents or things.

X. USE OF CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION IN FILINGS AND IN OPEN COURT

37. Nothing herein shall be construed to affect in any manner the admissibility at trial of any document, testimony, or other evidence.

38. The Clerk of Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.1.3, which has been designated, in whole or in part, as containing or revealing Confidential or Highly Confidential information under this Protective Order.

39. In the event that a party or third party wishes to use any Confidential or Highly Confidential information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court to be maintained under seal, such paper shall be enclosed in a sealed envelope or other appropriate

container. The outside of the sealed envelope or other appropriate container shall state and include:

a. the caption of this case, including the case number;

b. the title of the enclosed document;

c. the name of the party or third party entity filing the document (if the filing entity is not of record in the case, also include a contact name, telephone number, and e-mail address); and

d. the following legend:

> CONTAINS [HIGHLY] CONFIDENTIAL INFORMATION PURSUANT TO PROTECTIVE ORDER: This envelope [or container] is sealed pursuant to court order and contains [highly] confidential information. The contents of this envelope [or container] must not be shown to any person except as authorized by the Stipulated Protective Order in this action.

40. Any health information that is protected under state or federal privacy laws and is disclosed in discovery by a party or third party in these Proceedings shall not be used or disclosed in open court unless in accordance with a further order of the Court, such as an order of the Court sealing the courtroom. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

XI. DISPOSITION OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL MATERIALS AFTER CONCLUSION OF THESE PROCEEDINGS

41. Upon the final non-appealable termination of these Proceedings, all Confidential or Highly Confidential information received from an opposing or third party (and all copies and transcriptions thereof), shall be destroyed or returned to the Producing Party within ninety (90) calendar days. Outside Counsel, however, may retain (even if such documents or things contain Confidential or Highly Confidential information) all correspondence, pleadings and exhibits,

deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product except for protected health information (as described in Paragraph 3), which must be destroyed or returned within ninety (90) calendar days of the termination of these Proceedings. The Producing Party shall identify to the Receiving Party all such protected health information to be destroyed or returned by specific Bates numbers within forty-five (45) calendar days of the termination of these Proceedings. If the Producing Party does not provide this specific information to the Receiving Party within forty-five (45) days, then the Receiving Party is under no obligation to destroy or return the protected health information, but the health information shall remain Highly Confidential under the provisions of this Order. Documents and work product retained by Outside Counsel shall remain subject to the terms of this Order. Pursuant to this Paragraph, after ninety (90) calendar days following final non-appealable termination of these Proceedings, no person or entity other than Outside Counsel shall retain any Confidential or Highly Confidential information that it received from another party during the course of the Proceedings, including but not limited to Confidential or Highly Confidential information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential or Highly Confidential information.

XII. ADDITIONAL PROVISIONS

42. This Order shall be binding upon the Parties to these Proceedings and signatories to the Certification, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.

43. This Order shall apply to all information and material produced in these Proceedings, including all previously produced information and material prior to the execution of this Order by the Court.

44. The Parties agree that the following documents will not be discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants, or declarants, except to the extent such communications are excepted by Federal Rule of Civil Procedure 26(b)(4)(C)(i)-(iii); and (c) experts', affiants', and declarants' notes and working papers regarding such documents.

45. If any party breaches, or threatens to commit a breach, of any of the provisions of this Order, each non-breaching party or third party that produced information subject to this Order shall have the right to ask the Court for any remedies available under law or in equity, including having the Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party for breaches, threatened or actual. It is agreed and acknowledged that, in the event of any such breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

46. By written agreement of the Parties, or upon motion and order of the Court, the terms of this Order may be amended or modified, provided that any such stipulated modification concerning the use of any health information that is protected under state or federal privacy laws, or other applicable personal data protection laws, and is disclosed in discovery by a party or third party in these Proceedings shall be presented to the Court.

47. This Order shall continue in force until amended or superseded by express order of the Court. This Order shall survive termination of these Proceedings, including any final

judgment, appeal, or settlement to the extent the Confidential or Highly Confidential information is not or does not become known to the public.

48. Nothing in this Order shall prejudice the right of any party or third party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

49. In the event that a new party is added, substituted, or otherwise brought into these Proceedings, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

50. A legible photocopy of a document may be used as the "original" for all purposes in these Proceedings unless under the circumstances it would be unfair to admit the duplicate in lieu of the original (*see* Fed. R. Evid. 1003).

51. Each person or entity who receives any Confidential or Highly Confidential information agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Protective Order.

52. Other Proceedings. By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who in other proceedings becomes subject to a motion to disclose another party's information designated Confidential or Highly Confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard in the other proceeding on whether that information should be disclosed.

53. In order to expedite the discovery process, until this Stipulated Protective Order has been entered by the Court, the Parties agree that after counsel for the Parties execute this Stipulated Protective Order, it will be treated as though it had been "So Ordered."

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
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Attorneys for Plaintiff Allergan, Inc.

OF COUNSEL:

Jeffrey B. Elikan
Erica N. Andersen
Chanson Chang
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Attorneys for Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc.

OF COUNSEL:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN, LLP
525 W. Monroe Street
Chicago, IL 60661

SO ORDERED this _____ day of November 2017.

_____

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., Plaintiff, v. TARO PHARMACEUTICAL INDUSTRIES LTD. AND TARO PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-663 (VAC) (SRF) CONSOLIDATED

CERTIFICATION REGARDING PROTECTIVE ORDER

1. I, _____, have been asked by counsel for Plaintiff / Defendant(s) [circle one] in one or more of the above-captioned matters to review certain confidential documents or other information that is subject to the Stipulated Protective Order that has been or will be entered by the United States District Court for the District of Delaware in the above-captioned cases.

2. My present employer is _____ and the address of my present employer is _____. My present occupation or job title/description is _____.

3. I have received a copy of the Stipulated Protective Order in this action. I have carefully read and understood its provisions.

4. I will comply with all provisions of the Stipulated Protective Order, including but not limited to the following:

a. I will not disclose any information, documents, or things designated as Confidential or Highly Confidential information to anyone other than those persons specifically authorized by the Stipulated Protective Order.

b. I will not use any Confidential or Highly Confidential information for any purpose other than the above-captioned cases.

c. When requested to do so, I will return all materials containing Confidential or Highly Confidential information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential or Highly Confidential information to only those persons authorized by the Stipulated Protective Order to have such access. I will inform any of my employees or staff who encounter Confidential or Highly Confidential information of the terms of the Stipulated Protective Order.

6. I understand that my obligations regarding Confidential or Highly Confidential information under the Stipulated Protective Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information containing Confidential or Highly Confidential information, as well as any knowledge or information derived from any such information I receive during the above-captioned actions.

7. I understand that if I violate the provisions of the Stipulated Protective Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential or Highly Confidential information may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for District of Delaware with respect to the enforcement of the Stipulated Protective Order, or with respect to

any other order issued by the Court governing the use of Confidential or Highly Confidential information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ _____

Exhibit B

From: Beis, Kimberly A.
To: Lou, Jihong; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)
Date: Monday, September 25, 2017 5:01:40 PM
Attachments: 2017.09.25 - Draft Proposed Protective Order - Taro Revisions.DOCX

Counsel,

Attached please find a red-lined version of the proposed protective order in the actions by Allergan regarding ANDA No. 210191.

As mentioned last week, we are available for a meet-and-confer regarding the protective order tomorrow. Please let us know your availability.

Sincerely,

Kim

KIMBERLY A. BEIS
Associate
Katten Muchin Rosenman LLP
525 W. Monroe Street / Chicago, IL 60661-3693
p / (312) 902-5374 f / (312) 902-1061
kimberly.beis@kattenlaw.com / www.kattenlaw.com

From: Beis, Kimberly A.
Sent: Thursday, September 14, 2017 11:14 AM
To: 'Lou, Jihong'; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Dear Jihong,

Thank you for your email. The proposed protective order is currently under review by our client. While we are hopeful we will have comments to you this week, we note Judge Fallon's scheduling order requires any protective order to be presented by the parties within 10 days of the date of the scheduling order. Currently, the scheduling conference in set for September 20, 2017, therefore, a proposed protective order must be submitted to the Court no later than September 30, 2017.

We understand Allergan is claiming is it hindered and/or prejudiced because its in-house counsel and retained experts/consultants are currently unable to physically review ANDA No. 210191. However, Allergan's counsel has been in possession a portion of ANDA No. 210191, showing Taro's proposed products do not infringe, since July 20, 2017 and the entirety of ANDA No. 210191 since August 1, 2017. Allergan's counsel has been in a position to advise Allergan regarding ANDA No. 210191 since that time. Further, under the scheduling order proposed by Allergan, Taro would not even have been required to produce its ANDA until mid to late October. It is hard for Taro to understand what prejudice Allergan could claim at this time.

All that being said, we are working to review and finalize Taro's proposed revisions to the proposed protective order provided by Allergan. We will provide you with Taro's comments as soon as we

are able and will certainly meet any court deadlines as outlined in Judge Fallon's form scheduling order.

Sincerely,

Kim

KIMBERLY A. BEIS
Associate
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525 W. Monroe Street / Chicago, IL 60661-3693
p / (312) 902-5374 f / (312) 902-1061
kimberly.beis@kattenlaw.com / www.kattenlaw.com

From: Lou, Jihong [mailto:JLou@cov.com]
Sent: Wednesday, September 13, 2017 11:37 AM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Kim,

Thank you for the update on the status of Taro's comments to the proposed Protective Order. We understand from your email that Taro intends to send us its comments by this week, and we also acknowledge your representation that the parties should be able to jointly submit a proposed order to the Court by this Friday. We look forward to receiving your comments and to working together to finalize the proposed order.

As we have explained in our previous email, we believe that Taro's delay (now over a month) in providing comments on the proposed order has and continues to hinder Allergan's ability to conduct a proper analysis of Taro's ANDA. Accordingly, if there continues to be further delay, we reserve the right to seek relief directly from the Court.

Please note that we have sent you a proposed case schedule and our proposal on other discovery-related matters via a separate email on Monday morning. Please provide comments by COB today so that the parties will have time to meet and confer and finalize the scheduling order by the deadline of 6 pm this Friday.

With kind regards,
Jihong

Jihong Lou

Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5094 | jlou@cov.com
www.cov.com

COVINGTON

From: Beis, Kimberly A. [mailto:kimberly.beis@kattenlaw.com]
Sent: Friday, September 8, 2017 2:58 PM
To: Lou, Jihong <JLou@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Ms. Lou,

Thank you for your email. We understand Allergan first sent the proposed protective order in early August. We have been pulled onto some emergency matters recently, and while we have been looking at the proposed protective order, we have not yet finalized our review and proposed revisions.

While we understand it has taken us some time to review and respond to your proposal, given the stage of this litigation, we do not believe you client has experienced any prejudice and are not comfortable with the terms you propose in your email, prior to the entry of the protective order.

We do intend to provide you with our comments next week and believe we should be in a position to file a proposed protective order along with the proposed scheduling order on September 15th.

Please let us know when Plaintiff intends to send the first draft of the proposed scheduling order.

Thanks very much and have a great weekend.

Kim

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From: Lou, Jihong [mailto:JLou@cov.com]
Sent: Wednesday, September 06, 2017 4:27 PM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Counsel:

We write again regarding the proposed Stipulated Protective Order. It has been four weeks since we initially sent the proposed order on August 9, and Taro's delay in acting on the proposed order is prejudicing Allergan's ability to conduct a proper analysis of Taro's ANDA. We therefore propose that, while we wait for your response, the parties agree to allow the following individuals access to the ANDA under the terms of the currently proposed order: (1) two outside consultants; and (2) two in-house counsel at Allergan.

Please confirm by this Friday (September 8) whether Taro consents to the above proposal.

Regards,

Jihong Lou

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One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
T +1 202 662 5094 | jlou@cov.com
www.cov.com

COVINGTON

From: Lou, Jihong
Sent: Tuesday, August 29, 2017 7:06 PM
To: Beis, Kimberly A. <kimberly.beis@kattenlaw.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Kim,

I write to follow up on the proposed Stipulated Protective Order. It's been almost three weeks since we sent the proposed order, and we would appreciate hearing from you soon on whether Taro would consent to the proposed order.

Best regards,
Jihong

From: Beis, Kimberly A. [mailto:kimberly.beis@kattenlaw.com]
Sent: Monday, August 21, 2017 10:21 AM
To: Lou, Jihong <JLou@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Jihong,

Thank you for following up. We are reviewing Allergan's proposed protective order and will get back to you either later this week or early next week. Thank you.

Kim

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kimberly.beis@kattenlaw.com / www.kattenlaw.com

From: Lou, Jihong [mailto:JLou@cov.com]
Sent: Wednesday, August 16, 2017 8:47 AM
To: Benson, Stephen P.; Beis, Kimberly A.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: FW: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Counsel:

I write to follow up on the Stipulated Protective Order we sent last week. Please let us know if Taro consents to the attached Stipulated Protective Order.

Regards,
Jihong

From: Lou, Jihong
Sent: Wednesday, August 9, 2017 5:44 PM
To: Benson, Stephen P. <stephen.benson@kattenlaw.com>; Beis, Kimberly A. <kimberly.beis@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>
Subject: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Counsel:

In connection with the above-referenced actions, Allergan proposes that the parties stipulate to a protective order to facilitate discovery. Please let us know if you consent to the attached Stipulated Protective Order.

In addition, further to Mr. Benson's email last Friday, please let us know whether (1) Taro consents to a motion to consolidate the two actions referenced above, and (2) we may use the ANDA production in both actions after the Court grants our pro hac vice motions.

Regards,
Jihong

Jihong Lou

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www.cov.com

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 17-663 (VAC) (SRF)
	)	CONSOLIDATED
TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

~~IN THE UNITED STATES DISTRICT COURT~~
~~FOR THE DISTRICT OF DELAWARE~~

~~ALLERGAN, INC.,~~	~~)~~	
	~~)~~	
~~Plaintiff,~~	~~)~~	
	~~)~~	
~~v.~~	~~)~~	~~C.A. No. 17-663 (VAC) (SRF)~~
	~~)~~	
~~TARO PHARMACEUTICAL INDUSTRIES LTD.,~~	~~)~~	
	~~)~~	
~~Defendant.~~	~~)~~	
	~~)~~	

~~ALLERGAN, INC.,~~	~~)~~	
	~~)~~	
~~Plaintiff,~~	~~)~~	
	~~)~~	
~~v.~~	~~)~~	~~C.A. No. 17-1048 (VAC) (SRF)~~
	~~)~~	
~~TARO PHARMACEUTICALS, INC.,~~	~~)~~	
	~~)~~	
~~Defendant.~~	~~)~~	
	~~)~~	

[PROPOSED] STIPULATED PROTECTIVE ORDER

Pursuant to Federal Rule of Civil Procedure 26(c), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") and Defendants Taro Pharmaceutical Industries Ltd. ("~~Taro Industries~~TPIL") and Taro Pharmaceuticals, Inc. ("~~Taro Pharmaceuticals~~TPI") (collectively, "Taro" or "Defendants") request that the following Stipulated Protective Order ("Protective Order" or "Order") be entered in the above-captioned cases (the "Proceedings") to govern the exchange of discovery materials by the parties and third parties, the use or exhibition of documents and things during discovery, and testimony containing trade secrets, confidential or proprietary research, development, technical, financial, strategic, customer, or commercial information, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G), and personal health information protected under state or federal privacy laws, or other applicable personal data protection laws. Plaintiff and Defendants (all collectively, "the Parties") and this Court agree that the disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the Parties and third parties. Therefore, good cause exists for entry of this Protective Order to preserve the confidentiality of certain documents and information, to outline procedures and reasonable restrictions on the disclosure of sensitive materials, and to permit discovery to proceed without delay.

Accordingly, the Court hereby enters the following Protective Order, which shall control the disclosure, dissemination, and use of information in these Proceedings:

I. DESIGNATION OF MATERIAL AS "CONFIDENTIAL" OR "HIGHLY CONFIDENTIAL"

1. This Protective Order applies to any document, or portion thereof, any type of information, including electronically stored information and any form of discovery contemplated

under Rules 26 through 36 of the Federal Rules of Civil Procedure that, in the good-faith opinion of the party providing such material (the "Producing Party" or "Designating Party"), contains any trade secret or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information of the Producing Party, or a nonparty if such documents and information are within the possession, custody or control of the Producing Party. The party receiving such information is herein referred to as the "Receiving Party" or "Non-Designating Party." This Protective Order describes the information protected under its terms and the use and disclosure of such protected information.

2. The designation of material as "Confidential" as used in this Protective Order means information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c). ~~including but not limited to any documents and things relating to (i) the names, or other information tending to reveal the identities, of a party's suppliers, present or prospective customers, or distributors or the personal information of a party's employees; (ii) information relating to pending patent applications; (iii) commercial information, including, without limitation, strategic plans, marketing and financial information concerning a party's current products, processes and/or business relationships or potential future products, processes and/or business relationships; (iv) information constituting product specifications, formulations, and/or regarding the manufacture of the party's products; (v) technical notebooks and technical reports of a party, including product and manufacturing specifications, schematic diagrams, technical reference manuals, operations manuals, or other similar information; (vi) confidential marketing plans, market research and business strategy, including research regarding competitors; (vii) information the Designating Party believes is a proprietary trade secret; (viii) personal information and/or identities of physicians and patients;~~

~~(ix) all information relating to a party's research and development efforts; (x) all New Drug Applications ("NDAs"), Abbreviated New Drug Applications ("ANDAs"), or Drug Master Files ("DMFs"); and (xi) physical samples of any products described in an NDA (except for samples of publically available drug products) or ANDA.~~ Identification of types of documents in this Paragraph shall not be an admission by either of the Parties that such documents are relevant or admissible in these Proceedings. Confidential information may be contained in discovery information or materials produced or obtained in these Proceedings by or through any means and by or through any person or entity. The Confidential information contained therein and all copies, recordings, abstracts, excerpts, analyses, or other writings that contain, reveal, or otherwise disclose such Confidential information shall also be deemed Confidential information.

3. The designation of material as "Highly Confidential" by the Producing Party constitutes its reasonable, good-faith representation that the material disclosed is so sensitive and confidential that the disclosure, whether separately or in conjunction with other information being disclosed, is believed in good faith by the disclosing party to have the potential for causing serious competitive harm or giving a competitive advantage to others, and that access to such information should be more limited. Information that may be designated "Highly Confidential" means information (regardless of how it is generated, stored, or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c) that satisfies the requirements of Paragraph 2 and which comprises or contains particularly sensitive information of the Parties or third parties and their affiliates.~~,~~ ~~including but not limited to current or future financial documents (for example, P&L statements), business strategy, projected future sales, pricing, customer/vendor agreements, revenue, cost, or profit information for its products, information that any party is required to maintain in confidence under the Health Insurance~~

~~Portability and Accountability Act of 1996 ("HIPAA"), and any other information a Producing Party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the Receiving Party.~~ Identification of types of documents in this Paragraph shall not be an admission by either of the Parties that such documents are relevant or admissible in these Proceedings. The Producing Party may designate discrete pages or volumes of such information, on a document-by-document basis, as "Highly Confidential." This provision does not permit a Producing Party to designate entire categories of materials as "Highly Confidential" without making an individual assessment of sensitivity on a document-by-document basis. ~~Nor does this provision permit the designation as "Highly Confidential" any of the following materials concerning the subject matter of these Proceedings: technical or regulatory information relating to, referring to, or concerning NDA No. 207154 and the products described therein, or ANDA No. 210191 and the products described therein; including, but not limited to, the NDA or ANDA, any correspondence or other communication to or from FDA regarding the relevant application, and DMFs associated with or referenced in the NDA or ANDA.~~ Information designated as "Highly Confidential" may only be disclosed to Qualified Persons identified in Paragraph 15.

4. Any party or third party may designate as "Confidential" or "Highly Confidential" all or any part of any discovery or other materials produced or served in these Proceedings, or filed with the Court, including without limitation, documents and things, pleadings, motions, briefs, contentions, expert reports, interrogatory answers, deposition testimony, and responses to requests for admission, which contain sensitive proprietary, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26(c)(1)(G), as set forth in Paragraphs 2 and 3 above.

5. A party or third party shall designate a document or thing as "Confidential" or "Highly Confidential" when it is produced to the party seeking discovery by marking it prominently on its face with the legend in substantially the following form: "CONFIDENTIAL," "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER," "HIGHLY CONFIDENTIAL," or "HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER," as appropriate. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. If an entire multi-page document is to be treated as Confidential or Highly Confidential information, each page of such document should be marked. In addition, each page of each document and each thing produced pursuant to discovery in these Proceedings shall bear a unique identifying number.

6. Notwithstanding such designation, Confidential or Highly Confidential information does not include information obtained independently of these Proceedings as to which no obligation of confidentiality applies. Accordingly, nothing in this Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Confidential or Highly Confidential information if such information:

a. is determined by agreement of the Parties or order of the Court to be public information,

b. was lawfully in his or her possession prior to receiving the information or document under the provisions of this Order,

c. was, is, or becomes available to the public through no fault of a Receiving Party,

d. is disclosed by a third party who is not subject to any confidentiality obligations at the time of the disclosure, or

e. is discovered independently by the Receiving Party by means that do not constitute a violation of this Order.

7. Nothing in this Order shall prevent a party or third party from redacting from documents or things, which otherwise contain relevant discoverable information, any Confidential or Highly Confidential information that is irrelevant to these Proceedings or otherwise not discoverable, such as information relating to non-accused products, including products in development, pursuant to Federal Rule of Civil Procedure 26(b).

8. Prior to production, a party or third party may redact from all documents, e-mails, and personal electronic files all personal information, including the following: home address, home and cell phone numbers, pager numbers, names of spouses and children, credit card information, benefits information, compensation information, and personal information found in employee files. Any information referenced in this paragraph not redacted from a document shall be treated as Confidential, without the requirement of any such designation.

9. Unless otherwise agreed by the Parties, deposition transcripts taken in connection with these Proceedings will be temporarily designated and treated as Highly Confidential information for up to fourteen (14) calendar days after both Parties have received a final transcript of the deposition, in order to give the Parties or third parties the opportunity to properly designate any Confidential or Highly Confidential information in the transcript. A party may designate a deposition transcript as Confidential or Highly Confidential during the deposition at which such information was disclosed, or within those fourteen (14) calendar days after receipt of the final transcript, the Parties and/or third parties may designate any or all

portions of the transcript as Confidential or Highly Confidential information in accordance with this Protective Order. If a deposition transcript or deposition exhibits contain Confidential information, the deposition transcript will be marked on its first page with the legend "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." If the deposition transcript or deposition exhibits contain Highly Confidential information, the deposition transcript will be marked on its first page with the legend "HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." A deponent may review the transcript of his or her deposition at any time. Nothing in this Paragraph shall prevent a party from showing to its own employees, officers, directors, or agents transcripts from depositions taken of its own witnesses, unless such transcript contains Confidential or Highly Confidential information of the other party group. ~~.~~

10. Any material provided for inspection, as opposed to documents produced outright, in these Proceedings is to be treated by the inspecting/receiving party as Highly Confidential information pending the copying and delivery of any copies of the same by the Producing Party. After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel or independent consultants or experts eligible under Paragraph 14(a) or 14(c) below.

11. For ~~any~~ all documents produced before the entry of this Order ~~and marked under~~pursuant to District of Delaware Local Rule 26.2, the Receiving Party ~~will~~ shall treat them as Highly Confidential information, unless the Producing Party subsequently designates them otherwise.

12. Documents and things produced without a legend designating the material

Confidential or Highly Confidential information shall not be subject to this Protective Order, unless otherwise agreed to by the Parties or ordered by the Court.

II. USE OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL INFORMATION

13. Confidential and Highly Confidential information, including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be held in confidence by the Receiving Party, shall be used only by persons permitted access to the information under this Protective Order, and shall not be used for any purpose other than in connection with these Proceedings, any appeal therefrom, and remands thereto, including without limitation for any research, development, patent prosecution, commercial, marketing, regulatory, or other competitive purposes. Subject to Paragraphs 14 and 15 below, all persons receiving Confidential or Highly Confidential information are prohibited from using or disclosing such information in connection with practice before or communication with the United States Patent and Trademark Office ("USPTO"), the United States Food and Drug Administration, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction. Nothing contained in this Order shall preclude any party from using its own Confidential or Highly Confidential information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Order shall restrict any party's counsel from rendering advice to its clients with respect to these Proceedings and, in the course thereof, relying upon Confidential or Highly Confidential information, provided that in rendering such advice counsel shall not disclose any other party's Confidential or Highly Confidential information other than in a manner provided for in this Order.

III. ACCESS TO CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION

14. Confidential information, and any material containing such information, may be made available to, and inspected by, only the following "Qualified Persons":

(a) Outside counsel of record of the Receiving Party; and their partners, associates, paralegals, secretaries, and other supporting personnel who have actually received or reviewed such Confidential information (collectively, "Outside Counsel").

Outside Counsel who receives or reviews Confidential information shall not, during the pendency of the Proceedings, and for a period of eighteen (18) months after final termination of the Proceedings, including any appeals, participate in (1) the preparation or prosecution of any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient (2) any amendment or addition of claims in the patents-in-suit in any post-grant proceeding (including *inter partes* review) before the USPTO on any patent-in-suit or any patent issued from any application that is a continuation, continuation-in-part, division, or reissue application of or others claims the priority of application Nos. ____61/728,403 or 61/770,768 or is a divisional of 14/082/955 or (3) the preparation or submission of any citizen petition that would prohibit or delay approval of TPI's dapsone gel products under ANDA 210191. For clarity, "Outside Counsel," as used herein, do not include other individuals employed by the same law firm as outside counsel of record of the Receiving Party, who have not actually received or reviewed the Confidential information. In addition, this provision does not preclude Outside Counsel from receiving or reviewing Confidential information if they manage others who prepare or prosecute any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient, so long as the Outside Counsel does not participate in such preparation or prosecution or rely on Confidential information in advising others. Outside Counsel who receives or reviews Confidential

information may participate in post-grant proceedings (including *inter partes* proceedings, post-grant review, covered business method review, or *ex parte* reexamination) before the USPTO, or corresponding proceedings before any foreign patent authority, with the exception that Outside Counsel who receives or reviews Confidential information shall not participate, directly or indirectly, including by advising others, in the drafting or amendment of claims concerning any patent that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient;

(b) Allergan and Taro ~~(Taro Industries and Taro Pharmaceuticals, collectively)~~ may each designate up to two (2) in-house counsel or in-house IP personnel employed by the party, or by the party's subsidiary, parent, and/or affiliate, with responsibilities for managing this litigation, and their secretarial, clerical, paralegal, and other supporting personnel, provided that the designated in-house counsel are not directly responsible for competitive decision-making. "Competitive decision-making," as used herein, does not include (a) legal decision-making or advising responsibilities relating to topical products containing dapsone, including, for example, negotiating or executing agreements to settle litigation including responsibilities related to any financial terms of such agreements, advising about product launch dates or other product plans, or (b) interfacing with, for the purposes of carrying out responsibilities as an attorney, individuals responsible for competitive business decisions concerning topical products containing dapsone.

Designated in-house counsel who receives or reviews Confidential information shall not, during the pendency of the Proceedings, and for a period of eighteen (18) months after final termination of the Proceedings, including any appeals, participate in (1) the preparation or prosecution of any patent application before the USPTO or any corresponding foreign patent

authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient (2) any amendment or addition of claims in the patents-in-suit in any post-grant proceeding (including *inter partes* review) before the USPTO on any patent-in-suit or any patent issued from any application that is a continuation, continuation-in-part, division, or reissue application of or others claims the priority of application No. 61/728,403 or 61/770,768 or is a divisional of 14/082/955 ——or (3) the preparation or submission of any citizen petition that would prohibit or delay approval of TPI's dapsone gel products under ANDA 210191. For clarity, this provision does not preclude the designated in-house counsel from receiving or reviewing Confidential information if they manage others who prepare or prosecute any patent application before the USPTO or any corresponding foreign patent authority that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient, so long as the in-house counsel does not participate in such preparation or prosecution, including advising others on such preparation or prosecution. In-house counsel who receives or reviews Confidential information may participate in post-grant proceedings (including *inter partes* proceedings, post-grant review, covered business method review, or *ex parte* reexamination) before the USPTO, or corresponding proceedings before any foreign patent authority, with the exception that in-house counsel who receives or reviews Confidential information shall not participate, directly or indirectly, including by advising others, in the drafting or amendment of claims concerning any patent that involves subject matter relating to topical pharmaceutical products containing dapsone as the active ingredient.

As of the date of this Order, the designated in-house counsel are:

- For Allergan: (1) Brian Anderson; and (2) Shenade Walker.
- For Taro: (1) ~~TBD~~Craig Kuchii; and (2) TBD.

Allergan and Taro shall each have the right to add new persons or substitute new persons for in-house counsel designated under this Paragraph to receive Confidential information, provided that at any time no more than two designated people from each side shall have access to Confidential information pursuant to this Protective Order;

(c) Independent experts or consultants and their staff retained to assist the Receiving Party in the conduct of these Proceedings, provided such experts and consultants have complied with Paragraphs 18 and 19 herein;

(d) Witnesses or deponents who (1) are indicated on the face of the document or thing containing Confidential information as an author or recipient of the document or thing; (2) who have been identified, through discovery (including document production, written discovery, or deposition testimony) or some other basis for providing a reasonable belief, as having authored or received the document or thing, or similar or related documents or things from the same general time period, even if the individual is not identified as an actual author or recipient on the face of the document or thing at issue; or (3) who are (i) current employees of the Producing Party or who are (ii) former employees of the Producing Party who were employees of the Producing Party or its predecessor in interest, as of the date of the document or thing;

(e) The Court and personnel employed by the Court;

(f) Court reporters and videographers;

(g) Photocopy services;

(h) Professional translators who are retained by counsel for the Parties for the purposes of these Proceedings;

(i) Graphics or design consultants retained to prepare demonstrative or other exhibits for use in these Proceedings;

(j) Non-technical jury or trial consultants and persons employed or retained by them;

(k) Document imaging and database services and consultants retained to set up, maintain, and/or operate litigation databases; and

(l) Others as to whom the Designating Party has given written consent.

15. Highly Confidential information, and any material containing such information, may be made available to, and inspected by, only the Qualified Persons identified in Paragraphs 14(a) and 14(c)–(*l*). For the avoidance of doubt, Highly Confidential information will not be made available to or inspected by in-house counsel or in-house IP personnel for the parties.

16. Only Qualified Persons, the deponent, and his or her attorney (if any), shall be allowed to attend any portion of a deposition in which Confidential or Highly Confidential information is used or elicited from the deponent. Counsel for the Designating Party may also request that all persons other than the witness, the court reporter and videographer, Qualified Persons specified in Paragraph 15, and counsel for the witness (if a third party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Highly Confidential by the Designating Party. Counsel for the Designating Party may also request that all persons other than the witness, the court reporter and videographer, Qualified Persons specified in Paragraph 14, and counsel for the witness (if a third party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Confidential by the Designating Party. The failure of individuals other than those specified in the previous two sentences to leave the deposition room during any portion of the deposition

which inquires into matters deemed Confidential or Highly Confidential by the Designating Party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question(s) posed concerning such matters.

17. This Order shall not limit a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential or Highly Confidential information under the terms of this Order, so long as such examination concerns Confidential or Highly Confidential information that the witness authored, received, or previously had access to or knowledge of, the witness was involved in the subject matter described therein, or the witness is a present or former employee of the party that produced the information, document, or thing, as demonstrated by the information itself, by foundation testimony during a deposition, hearing or trial, or if the Producing Party consents to such disclosure. This Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored, received, was involved in the subject matter described therein, or previously had access to or knowledge of Confidential or Highly Confidential information.

18. Before disclosing another party's Confidential or Highly Confidential information to persons or entities described in Paragraph 14(c), the party shall first obtain a signed Certification in the form of the annexed Exhibit A. The Certification shall be signed by the ~~company, firm, group, or person~~independent consultant or expert retained by the party, and a single Certification by the ~~company, firm, group, or person~~independent consultant or expert shall be sufficient to cover all employees of the ~~company, firm, or group~~independent consultant or expert. Counsel retaining the person(s) described in Paragraph 14(c) shall retain the original of each such signed Certification.

19. Before disclosing another party's Confidential or Highly Confidential information to any outside consultant or expert described in Paragraph 14(c), the party shall first provide to the Producing Party (a) a signed copy of the Certification found in Exhibit A of this Order, (b) a current resume (*curriculum vitae*) of the consultant or expert including a list of publications, and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the Producing Party has received the requisite documents and consultant/expert information, the Producing Party shall then have seven (7) calendar days to provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made, (a) there shall be no disclosure of the Confidential or Highly Confidential information to the consultant or expert, except by further order of the Court or by agreement by the Parties, (b) the Parties agree to promptly meet and confer in good faith regarding the basis for (and resolution of) the objection, and (c) if the Parties cannot reach an agreement, the party objecting to the disclosure of information to the consultant/expert may pursue the issue via the Court's established discovery dispute procedures within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this Paragraph, the objecting party shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or to timely file a motion with the Court will act as a waiver of the objection, and the consultant or expert will become a Qualified Person.

IV. INADVERTENT PRODUCTION OF INCORRECTLY DESIGNATED MATERIAL

20. Inadvertent production of any document, thing, or information without a designation of Confidential or Highly Confidential information will not be deemed to waive a

later claim as to its confidential nature, or stop the Producing Party from designating said document or information as Confidential or Highly Confidential information at a later date.

21. Any Producing Party may change a designation to Confidential or Highly Confidential (or withdraw a designation) regarding any material that it has produced by notifying counsel for each party in writing. Upon receipt of such notice, the Non-Designating Party shall: (i) not make any further disclosure or communication of such newly designated material except as provided for in this Order; (ii) take reasonable steps to notify any persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation under this Order; (iii) for material newly designated as Highly Confidential, promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not Qualified Persons under Paragraph 15; and (iv) for material newly designated as Confidential, promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not Qualified Persons under Paragraph 14. Properly marked documents, reflecting the new designation, shall be promptly provided by the Producing Party.

V. CHALLENGING A "CONFIDENTIAL" OR "HIGHLY CONFIDENTIAL" DESIGNATION

22. A party receiving documents or things shall not be obligated to challenge the propriety of a Confidential or Highly Confidential information designation (or re-designation) at the time the document or thing is produced, and a failure to do so shall not preclude a subsequent challenge thereto. If a Receiving Party disagrees at any time with a Confidential or Highly

Confidential information designation made by another party or a third party, the following procedure shall be used:

a. The party seeking to change the designation of another party's documents, things, or information shall provide the Producing Party written notice specifying the documents, things, or information for which a change in designation is sought, and the reasons for the request. The Producing Party shall have seven (7) calendar days after receipt of the written notice within which to object in writing to the change in designation or removal of protection afforded by this Order and to specify why protection under this Order is appropriate.

b. If the Producing Party objects in writing within seven (7) calendar days of receiving such a written notice, both Parties shall meet and confer in an attempt to resolve the dispute without involvement of the Court.

c. If the Parties and/or third parties cannot reach agreement concerning the change in designation, the party seeking the removal of protection for the Confidential or Highly Confidential information may pursue the issue via the Court's established discovery dispute procedures.

d. The Parties shall continue to treat the document(s) or thing(s) at issue as Confidential or Highly Confidential information (according to the original designation(s)) until the dispute is resolved by Order of this Court, or by agreement of the Parties and/or third parties.

e. On any motions arising out of the designation of any material as Confidential or Highly Confidential information under this Order, the burden of justifying the designation shall lie with the Producing Party.

VI. INADVERTENT USE OF CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION

23. If Confidential or Highly Confidential information is used inadvertently during the course of the Proceedings (including at depositions) inconsistent with or in contravention of other provisions of this Order, the information shall not lose its confidential status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its confidentiality after such inadvertent use. If Confidential or Highly Confidential information is inadvertently disclosed to a deposition witness, and the witness has testified that he or she has knowledge concerning that information, the witness may be examined and cross-examined with respect to the document or information disclosed for the remainder of the deposition.

24. If Confidential or Highly Confidential information is disclosed to any person other than in the manner authorized by this Order, the party responsible for the disclosure shall within five (5) calendar days of learning of such disclosure inform the Producing Party of all pertinent facts relating to such disclosure. As soon as possible thereafter, the Parties shall also use reasonable efforts to obtain the prompt return of any such Confidential or Highly Confidential information, and obtain a signed Certification attached hereto as Exhibit A from each unauthorized person or party who received Confidential or Highly Confidential information. The requirements set forth in this Paragraph shall not prevent the Producing Party from requesting that the party responsible for the inadvertent disclosure take additional remedial steps and/or applying to the Court for additional relief.

VII. INADVERTENT PRODUCTION OR USE OF PRIVILEGED INFORMATION

25. If information subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information from discovery is inadvertently produced in any way, such production shall not constitute a waiver (subject matter or otherwise)

of any claim of privilege, work product immunity, or other ground for withholding production to which the Producing Party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Federal Rule of Civil Procedure 26(b)(5)(B) and/or Federal Rule of Evidence 502.

26. If a written claim of inadvertent production of privileged information is made by a Producing Party to a Receiving Party, the Receiving Party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested document physically at the deposition must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 26(a), destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced information or documents possessed by the Receiving Party and by those persons to whom the Receiving Party may have disclosed such information.

27. Recognizing the need for the Parties to prepare for their cases based on the discovery that is produced, if any information, document, or thing is used openly in the case, *e.g.*, at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production based on privilege, must be made within two (2) weeks after such use.

28. Nothing herein shall prevent the Receiving Party from challenging the propriety of the attorney-client privilege, work product immunity, or other privilege designation, or from

presenting the information to the Court under seal for a determination of the privilege claim through a written challenge to the Court. The Receiving Party must preserve the confidentiality of the document or information until the claim is resolved.

VIII. INADVERTENT PRODUCTION OF ELECTRONICALLY STORED INFORMATION

29. If electronically stored information ("ESI") is inadvertently produced as the result of an error in the ESI production process, including but not limited to, predictive coding errors, optical character recognition ("OCR") errors, or errors in the application of search terms to ESI databases, such production shall not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the Producing Party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Federal Rule of Civil Procedure 26(b)(5)(B) and/or Federal Rule of Evidence 502.

30. If a written claim of inadvertent production of ESI is made by a Producing Party to a Receiving Party, the Receiving Party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed ESI; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested ESI physically at the deposition must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 30(a), destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced ESI possessed by the Receiving Party and by those persons to whom the Receiving Party may have disclosed such information.

31. Recognizing the need for the Parties to prepare for their cases based on the discovery that is produced, if any ESI is used openly in the case, *e.g.*, at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production of such ESI must be made within two (2) weeks after such use.

32. Nothing herein shall prevent the Receiving Party from challenging the propriety of the claim of inadvertent production of ESI. The Receiving Party must preserve the confidentiality of the document or information until the claim is resolved.

IX. PRODUCTION OR DISCLOSURE OF A THIRD PARTY'S INFORMATION

33. Any subpoena or other notice to a third party requesting production of documents shall include a copy of this Protective Order.

34. If a third party produces documents pursuant to a subpoena or other request issued by one of the Parties (or by Court order) and if the third party has not requested its documents be treated as Confidential or Highly Confidential, then it shall be presumed that the documents produced contain information for which the third party has determined require no designation under this Protective Order. The third party's documents and things shall be handled by all Parties to these Proceedings according to the appropriate designations under this Protective Order. The party issuing the subpoena or other request for documents or things to the third party shall provide any non-requesting party an opportunity to review and make copies of any documents produced in response to that subpoena or request.

35. A party in these Proceedings may temporarily withhold production of otherwise discoverable information sought in a discovery request (*e.g.*, interrogatory, request for production, or request for admission) if the party is under an obligation to a third party not to disclose such information (*e.g.*, by prior agreement of confidentiality). In such an event (except

for information subject to another protective order or confidentiality order by another court), the Producing Party shall:

a. timely serve a written objection to the production of the requested information on the basis of its obligation to a third party not to disclose such information;

b. promptly provide to the third party whose confidentiality interests are implicated (i) notice of the pending request to disclose the information, and (ii) a copy of this Protective Order; and

c. if the third party does not agree to disclosure of its information, then the party requesting the documents or things from the third party may (i) serve a subpoena on the third party, if the requesting party has not already done so, or (ii) file a motion to compel production of the requested documents against a party and/or third party in the appropriate Court.

36. Any party to these Proceedings that receives a subpoena or other request from a third party that seeks the disclosure/production of Confidential or Highly Confidential information already disclosed in these Proceedings that the party did not itself produce shall give prompt telephonic and written notice to that original Producing Party of such subpoena or other request, but in no event more than seven (7) calendar days after actual receipt of the subpoena or other request. If the original Producing Party opposes disclosure of its documents called for by the subpoena or other request, then the party served with the subpoena shall not disclose the pertinent information until a Court has resolved the issue. Absent a Court order, production or disclosure of another party's information shall not be made until the original Producing Party has agreed to such production to a third party. The original Producing Party shall bear the burden to oppose, if it deems appropriate, the subpoena or other request on the grounds of confidentiality. This Paragraph shall not apply to disclosure of information pursuant to a third party's subpoena

or request for Confidential or Highly Confidential information, if the party receiving the subpoena or request itself produced the documents or things called for by the subpoena or request, i.e., this Paragraph shall not apply to the disclosure of a party's own documents or things.

X. USE OF CONFIDENTIAL OR HIGHLY CONFIDENTIAL INFORMATION IN FILINGS AND IN OPEN COURT

37. Nothing herein shall be construed to affect in any manner the admissibility at trial of any document, testimony, or other evidence.

38. The Clerk of Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.1.3, which has been designated, in whole or in part, as containing or revealing Confidential or Highly Confidential information under this Protective Order.

39. In the event that a party or third party wishes to use any Confidential or Highly Confidential information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court to be maintained under seal, such paper shall be enclosed in a sealed envelope or other appropriate container. The outside of the sealed envelope or other appropriate container shall state and include:

a. the caption of this case, including the case number;

b. the title of the enclosed document;

c. the name of the party or third party entity filing the document (if the filing entity is not of record in the case, also include a contact name, telephone number, and e-mail address); and

d. the following legend:

> CONTAINS [HIGHLY] CONFIDENTIAL INFORMATION PURSUANT TO PROTECTIVE ORDER: This envelope [or container] is sealed pursuant to court order and contains [highly] confidential information. The contents of this envelope [or container] must not be shown to any person except as authorized by the Stipulated Protective Order in this action.

40. Any health information that is protected under state or federal privacy laws and is disclosed in discovery by a party or third party in these Proceedings shall not be used or disclosed in open court unless in accordance with a further order of the Court, such as an order of the Court sealing the courtroom. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

XI. DISPOSITION OF CONFIDENTIAL AND HIGHLY CONFIDENTIAL MATERIALS AFTER CONCLUSION OF THESE PROCEEDINGS

41. Upon the final non-appealable termination of these Proceedings, all Confidential or Highly Confidential information received from an opposing or third party (and all copies and transcriptions thereof), shall be destroyed or returned to the Producing Party within ninety (90) calendar days. Outside Counsel, however, may retain (even if such documents or things contain Confidential or Highly Confidential information) all correspondence, pleadings and exhibits, deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product except for protected health information (as described in Paragraph 3), which must be destroyed or returned within ninety (90) calendar days of the termination of these Proceedings. The Producing Party shall identify to the Receiving Party all such protected health information to be destroyed or returned by specific Bates numbers within forty-five (45) calendar days of the termination of these Proceedings. If the Producing Party

does not provide this specific information to the Receiving Party within forty-five (45) days, then the Receiving Party is under no obligation to destroy or return the protected health information, but the health information shall remain Highly Confidential under the provisions of this Order. Documents and work product retained by Outside Counsel shall remain subject to the terms of this Order. Pursuant to this Paragraph, after ninety (90) calendar days following final non-appealable termination of these Proceedings, no person or entity other than Outside Counsel shall retain any Confidential or Highly Confidential information that it received from another party during the course of the Proceedings, including but not limited to Confidential or Highly Confidential information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential or Highly Confidential information.

XII. ADDITIONAL PROVISIONS

42. This Order shall be binding upon the Parties to these Proceedings and signatories to the Certification, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.

43. This Order shall apply to all information and material produced in these Proceedings, including all previously produced information and material prior to the execution of this Order by the Court.

44. The Parties agree that the following documents will not be discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants, or declarants, except to the extent such communications are excepted by Federal Rule of Civil Procedure 26(b)(4)(C)(i)-(iii); and (c) experts', affiants', and declarants' notes and working papers regarding such documents.

45. If any party breaches, or threatens to commit a breach, of any of the provisions of this Order, each non-breaching party or third party that produced information subject to this Order shall have the right to ask the Court for any remedies available under law or in equity, including having the Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party for breaches, threatened or actual. It is agreed and acknowledged that, in the event of any such breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

46. By written agreement of the Parties, or upon motion and order of the Court, the terms of this Order may be amended or modified, provided that any such stipulated modification concerning the use of any health information that is protected under state or federal privacy laws, or other applicable personal data protection laws, and is disclosed in discovery by a party or third party in these Proceedings shall be presented to the Court.

47. This Order shall continue in force until amended or superseded by express order of the Court. This Order shall survive termination of these Proceedings, including any final judgment, appeal, or settlement to the extent the Confidential or Highly Confidential information is not or does not become known to the public.

48. Nothing in this Order shall prejudice the right of any party or third party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

49. In the event that a new party is added, substituted, or otherwise brought into these Proceedings, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

50. A legible photocopy of a document may be used as the "original" for all purposes in these Proceedings unless under the circumstances it would be unfair to admit the duplicate in lieu of the original (*see* Fed. R. Evid. 1003).

51. Each person or entity who receives any Confidential or Highly Confidential information agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Protective Order.

52. Other Proceedings. By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated Confidential or Highly Confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

53. In order to expedite the discovery process, until this Stipulated Protective Order has been entered by the Court, the Parties agree that after counsel for the Parties execute this Stipulated Protective Order, it will be treated as though it had been "So Ordered."

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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Attorneys for Plaintiff Allergan, Inc.

OF COUNSEL:

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Attorneys for Defendants Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc.

OF COUNSEL:

Stephen P. Benson
Kimberly A. Beis
KATTEN MUCHIN ROSENMAN, LLP
525 W. Monroe Street
Chicago, IL 60661

SO ORDERED this _____ day of ~~August~~ September 2017.

_____

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 17-663 (VAC) (SRF)
	)	CONSOLIDATED
TARO PHARMACEUTICAL INDUSTRIES LTD. and TARO PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

~~IN THE UNITED STATES DISTRICT COURT~~
~~FOR THE DISTRICT OF DELAWARE~~

~~ALLERGAN, INC.,~~	~~)~~	
	~~)~~	
~~Plaintiff,~~	~~)~~	
	~~)~~	
~~v.~~	~~)~~	~~C.A. No. 17-663 (VAC) (SRF)~~
	~~)~~	
~~TARO PHARMACEUTICAL INDUSTRIES LTD.,~~	~~)~~	
	~~)~~	
~~Defendant.~~	~~)~~	
	~~)~~	

~~ALLERGAN, INC.,~~	~~)~~	
	~~)~~	
~~Plaintiff,~~	~~)~~	
	~~)~~	
~~v.~~	~~)~~	~~C.A. No. 17-1048 (VAC) (SRF)~~
	~~)~~	
~~TARO PHARMACEUTICALS, INC.,~~	~~)~~	
	~~)~~	
~~Defendant.~~	~~)~~	
	~~)~~	

CERTIFICATION REGARDING PROTECTIVE ORDER

1. I, _____, have been asked by counsel for Plaintiff / Defendant(s) [circle one] in one or more of the above-captioned matters to review certain confidential documents or other information that is subject to the Stipulated Protective Order that has been or will be entered by the United States District Court for the District of Delaware in the above-captioned cases.

2. My present employer is _____ and the address of my present employer is _____. My present occupation or job title/description is _____.

3. I have received a copy of the Stipulated Protective Order in this action. I have carefully read and understood its provisions.

4. I will comply with all provisions of the Stipulated Protective Order, including but not limited to the following:

a. I will not disclose any information, documents, or things designated as Confidential or Highly Confidential information to anyone other than those persons specifically authorized by the Stipulated Protective Order.

b. I will not use any Confidential or Highly Confidential information for any purpose other than the above-captioned cases.

c. When requested to do so, I will return all materials containing Confidential or Highly Confidential information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential or Highly Confidential information to only those persons authorized by the Stipulated Protective Order to

have such access. I will inform any of my employees or staff who encounter Confidential or Highly Confidential information of the terms of the Stipulated Protective Order.

6. I understand that my obligations regarding Confidential or Highly Confidential information under the Stipulated Protective Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information containing Confidential or Highly Confidential information, as well as any knowledge or information derived from any such information I receive during the above-captioned actions.

7. I understand that if I violate the provisions of the Stipulated Protective Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential or Highly Confidential information may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for District of Delaware with respect to the enforcement of the Stipulated Protective Order, or with respect to any other order issued by the Court governing the use of Confidential or Highly Confidential information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____ _____

Exhibit C

From: Beis, Kimberly A.
To: Andersen, Erica; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del.): Protective Order
Date: Tuesday, October 24, 2017 10:11:15 PM

Erica,

Yes, the parties disagree regarding Paragraph 11. For reference, as outlined in Taro's October 5 email, Taro has rejected Allergan's additions to the paragraphs relating to the designations of documents as Confidential and Highly Confidential, including the section relating to documents produced pursuant to Local Rule 26.2. It remains Taro's position its ANDA is Highly Confidential, but it is willing to designate certain formulation information as being Confidential solely for the purpose of allowing Allergan's in house counsel access – Taro has also expressed its willingness to consider granting in house counsel access to other sections of Taro's ANDA Allergan requests. Taro believes, as the designating party, it and *not* Allergan is entitled to designate Taro's ANDA as it deems appropriate. The draft Protective Order incorporates this concept in that it allows each party to designate its own documents. If the receiving party disagrees with any designation, there is a protocol in the draft Protective Order for resolving that dispute.

Regarding persons to have access under Paragraph 14(b), Taro disagrees both individuals should be required to be attorneys. The individuals Taro would designate work in the IP Group and would be serving in a counseling role in terms of the litigation. Taro would agree to designating one in-house counsel and one person who is working at the direction of and being supervised by in-house counsel.

Please let us know if Allergan will agree to those terms for Paragraph 14(b).

Sincerely,

Kim

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From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Monday, October 23, 2017 9:07 AM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del.): Protective Order

Kim,

In the proposed Protective Order attached to your 10/10 email, you did not present Taro's revisions to Paragraph 11 in redline. As shown in the redline attached to Allergan's 10/3 email, Allergan's proposed Paragraph 11 reads as follows:

> 11. For any documents produced before the entry of this Order and marked under District of Delaware Local Rule 26.2, the Receiving Party will treat them as Confidential information, unless the Producing Party subsequently designates them otherwise.

The version you sent us on 10/10 proposes the following language:

> 11. For all documents produced before the entry of this Order pursuant to District of Delaware Local Rule 26.2, the Receiving Party shall treat them as Highly Confidential information, unless the Producing Party subsequently designates them otherwise.

Our understanding is that the parties disagree about paragraph 11 (based on the in-house counsel issue), but in light of Taro's failure to redline, we wanted to confirm in writing.

Separately, please provide an update ASAP regarding the in-house counsel/personnel issue, as the first letter to the Court is due next Wednesday.

Regards,
Erica

Erica N. Andersen

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COVINGTON

From: Beis, Kimberly A. [mailto:kimberly.beis@kattenlaw.com]
Sent: Tuesday, October 10, 2017 6:42 PM
To: Andersen, Erica <eandersen@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Erica,

Attached please find an updated revision of the proposed protective order.

Regarding Paragraph 8, we agree the many of the documents that would contain this type of information would likely be designated as Confidential, and can agree not to add the language previously proposed.

Regarding Paragraph 9, the attached has Taro's proposed language based on your comment below. Taro would advocate for removing the entire sentence, but should it be left in, Taro proposes the below (also reflected in the attached).

> Nothing in this Paragraph shall prevent a party from showing to its own employees, officers, directors, or agents transcripts from depositions taken of its own fact witnesses, unless such

witness is a person identified in Paragraph 14(b), or their secretarial, clerical, paralegal, and other supporting personnel, and the transcript contains Confidential or Highly Confidential information of the other party group.

We are still conferring with our client regarding individuals to have access and be designated to receive Confidential information and will get back to you soon.

Please let us know if you agree to the revision in Paragraph 9 or if you would prefer to remove the sentence in its entirety.

Sincerely,
Kim

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From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Thursday, October 05, 2017 1:53 PM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Kim,

With respect to paragraph 8, the issue is that if the receiving party overlooks the information in a public document and distributes it, that party will be in violation of the PO--even if the document is very long and the information was overlooked by mistake. We do not think it is appropriate to make the receiving party scour the documents for such information to avoid PO violations when that same information was missed by the producing party. And if a document is already confidential or highly confidential, this is a non-issue, because the information already will be designated appropriately.

With respect to paragraph 9, only two individuals from Allergan have access to Taro-confidential information, and they are specifically mentioned in the Protective Order in (Paragraph 14(b)). If Taro wants to add a provision that indicates any deposition transcript of a person identified in 14(b) containing confidential information of the opposing party may not be disseminated more broadly, we could potentially agree to that. Please circulate proposed language.

We believe a meet-and-confer is still necessary. We are coordinating with our Delaware counsel, and will be back to you on time.

Regards,
Erica

Erica N. Andersen

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From: Beis, Kimberly A. [mailto:kimberly.beis@kattenlaw.com]
Sent: Thursday, October 05, 2017 2:26 PM
To: Andersen, Erica <eandersen@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Erica,

Thank you for further clarifying Allergan's position regarding Paragraphs 8 and 9.

Regarding Paragraph 8, the intention was to automatically designate the personal information in the document as Confidential, not the entire document.

Regarding Paragraph 9, we disagree there could not be an instance where a deponent had access to the opposing party's Confidential or Highly Confidential Information under the protective order. In that instance, there would be no waiver of the Confidentiality, and the transcript/exhibits should not be disseminated to individuals who do not have access to Confidential or Highly Confidential information.

Please let us know if Allergan agrees to the language proposed by Taro, or if there is language Allergan would like to suggest.

Hopefully we can work through these issues before a meet and confer. With that in mind, we can be available for a meet and confer tomorrow afternoon between 1:00pm and 3:00pm ET.

Sincerely,

Kim

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kimberly.beis@kattenlaw.com / www.kattenlaw.com

From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Thursday, October 05, 2017 10:26 AM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Kim,

With respect to paragraph 8, if a document is Confidential or Highly Confidential, the clause becomes superfluous. If the document is public, Taro is essentially saying it would be a violation of the PO if the receiving party fails to identify and redact every instance of the enumerated personal information, even if the document is hundreds or thousands of pages. We are happy to use best efforts to make sure this sort of information is not disseminated more broadly, but we do not think the new clause is appropriate as written.

With respect to paragraph 9, if Taro chooses shows its own confidential information to Allergan witnesses, then it has made a choice to waive confidentiality of that information. Therefore, we do not understand the addition Taro has made.

Please circulate a time for a meet-and-confer with Delaware counsel on the Protective Order and the Initial Disclosures.

Thanks,
Erica

Erica N. Andersen

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From: Beis, Kimberly A. [mailto:kimberly.beis@kattenlaw.com]
Sent: Thursday, October 05, 2017 11:13 AM
To: Andersen, Erica <eandersen@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Erica,

Thank you for providing us Allergan's proposed revisions to the Protective Order on Tuesday. We have reviewed Allergan's revisions and have accepted the changes relating to the prosecution bar as well as the changes in the "Other Proceedings" paragraph. We do have some additional questions regarding some of the other proposed revisions made.

Regarding Paragraphs 8 and 9, could Allergan elaborate on its reasoning for rejecting the additional language relating to treating personal information as Confidential and for limiting exposure of depositions if the transcript/exhibits contain Confidential/Highly Confidential information of other parties? The language in question is highlighted in the attached.

Taro added the language in the following sentence in relationship to personal information to be redacted in Paragraph 8: "Any information referenced in this paragraph not redacted from a document shall be treated as Confidential, without the requirement of any such designation." Taro feels this type of information can be properly considered Confidential should a party not redact it prior to production. This is just an extra safeguard for the personal information on individuals referenced in each party's documents.

Taro also added the information after the comma in the following sentence: "Nothing in this Paragraph shall prevent a party from showing to its own employees, officers, directors, or agents transcripts from depositions taken of its own witnesses, unless such transcript contains Confidential or Highly Confidential information of the other party group." Taro added this information to ensure protection of each parties Confidential or Highly Confidential pursuant to the terms of the proposed protective order. Should the parties be unable to agree this information would be redacted from transcripts, Taro would propose removing the entire sentence, thus ensuring the parties are following the procedures for access and dissemination of Confidential and Highly Confidential as outlined in the protective order.

As laid out in the parties' previous meet and confer and in Taro's written correspondence, Taro has rejected Allergan's additions to the paragraphs relating to the designations of documents as Confidential and Highly Confidential, including the section relating to documents produced pursuant to Local Rule 26.2. Taro's position is its ANDA is Highly Confidential, but it is willing to designate certain formulation information as being Confidential solely for the purpose of allowing Allergan's in counsel access – Taro has also expressed its willingness to consider granting in house counsel access to other sections of Taro's ANDA Allergan requests. Taro believes, as the designating party, it and *not* Allergan is entitled to designate Taro's ANDA as it deems appropriate. The draft Protective Order incorporates this concept in that it allows each party to designate its own documents. If the receiving party disagrees with any designation, there is a protocol in the draft Protective Order for resolving that dispute.

Please let us know if you can add any clarity to Allergan's positions regarding Paragraphs 8 and 9, so we can ensure we are presenting the necessary issues to the Court regarding the proposed protective order.

Sincerely,

Kim

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From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Tuesday, October 03, 2017 11:50 AM
To: Benson, Stephen P.; Beis, Kimberly A.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Stephen,

Attached is a redline showing Plaintiff's edits to Taro's draft of the Protective Order.

Again, we ask that you provide a time today or tomorrow morning for a meet-and-confer (with Delaware counsel) so that we may contact the Court and resolve these issues as soon as possible.

Regards,
Erica

Erica N. Andersen

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COVINGTON

From: Andersen, Erica
Sent: Friday, September 29, 2017 5:33 PM
To: 'Benson, Stephen P.' <stephen.benson@kattenlaw.com>; Beis, Kimberly A. <kimberly.beis@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Apologies on your name--being an Andersen (and not an Anderson) I am sensitive to these things and will spell it correctly in the future.

Please provide times on Monday or Tuesday for a meet-and-confer on the Initial Disclosures and Protective Order. Again, please provide times when Delaware counsel is available so we can contact the Court and resolve these issues as soon as possible.

From: Benson, Stephen P. [mailto:stephen.benson@kattenlaw.com]
Sent: Friday, September 29, 2017 5:26 PM
To: Andersen, Erica <eandersen@cov.com>; Beis, Kimberly A. <kimberly.beis@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>

Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Dear Erica,

Taro has no objection to experts having access to the full ANDA pursuant to the proposal we outlined.

Yes, edits to the Protective Order would be appreciated so we can narrow the issues for the Court to address.

I think both parties have been clear: (1) Taro's position is its ANDA is Highly Confidential, but it is willing to designate certain formulation information as being Confidential solely for the purpose of allowing Allergan's in counsel access – Taro has also expressed its willingness to consider granting in house counsel access to other sections of Taro's ANDA Allergan requests; (2) Allergan's position is Taro's ANDA is not Highly Confidential. Taro believes, as the designating party, it and *not* Allergan is entitled to designate Taro's ANDA as it deems appropriate. The draft Protective Order incorporates this concept in that it allows each party to designate its own documents. If the receiving party disagrees with any designation, there is a protocol in the draft Protective Order for resolving that dispute.

Taro is fully prepared to defend its position in Court. Taro continues to believe the best way forward is for each party to be responsible for designating its own documents as it deems appropriate. To the extent Allergan believes portions of the ANDA (or the entire ANDA) is not Highly Confidential, it can raise that position pursuant to the protocol in the Protective Order. In any event, Allergan's outside counsel has had access to the ANDA for some time and has been in a very good position to advise its client based on the content. As to designation of Taro's ANDA, I don't think any further meet and confer is necessary. As to Allergan's other changes, we look forward to seeing those revisions.

Finally, we can agree to disagree about the OCA. Our position is Allergan has always been unreasonable, but we fully understand Allergan disagrees with that position. We see no additional benefit to repeating our positions to one another on that point.

Although I am in no way offended, please note the correct spelling of my name.

Sincerely,

STEPHEN P. BENSON
Partner
Katten Muchin Rosenman LLP
525 W. Monroe Street / Chicago, IL 60661-3693
p / (312) 902-5448 f / (312) 902-1061

stephen.benson@kattenlaw.com / www.kattenlaw.com

From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Friday, September 29, 2017 4:04 PM
To: Benson, Stephen P.; Beis, Kimberly A.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone; Holub, Matthew M.
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Steven,

As we said on Wednesday, we believe in-house counsel should have access to all sections of the ANDA. As we stated on the call, we are potentially willing to agree to a proposal where in-house counsel has access to less than the entire ANDA, but Taro should be identifying the sections it is either comfortable or uncomfortable with sharing. Again, as we stated on Wednesday, we do not think we should have to negotiate against ourselves--we have made our position clear and Taro should do the same.

We do not understand your reference to the OCA negotiations below. Neither OCA originally provided for in house or expert access, and Taro's willingness to share portions of the ANDA one day before the first complaint needed to be filed (and not at all before the second complaint) neither allowed for meaningful review nor was reasonable.

My e-mail below was very clear that Allergan would "***consider*** edits to the prosecution bar to make Taro more comfortable," not that Allergan was agreeing to those revisions wholesale. We will work to send you edits to those provisions, but unless Taro is changing its position on in-house counsel access based on the prosecution bar, we do not think this resolves the major issue between the parties.

Our September 6 and 22 e-mails also did not restrict expert access to particular sections of the ANDA, and we do not understand why such experts should be limited to viewing particular sections of the ANDA under the draft Protective Order. Please confirm that you agree Allergan's experts will be able to access all Taro-confidential/highly confidential materials as soon as we provide the information for those experts you have requested below (and the requisite period for objection has passed).

With respect to the Initial Disclosures, we continue to believe that production of the ANDA and future identification of the person with the most knowledge is not a substitute for identifying individuals pursuant to Rule 26.

Please propose times on Monday for a meet-and-confer. We would like Delaware counsel on the phone so that they may call the Court on these two issues if the parties are indeed at an impasse (as we appear to be).

Regards,
Erica

Erica N. Andersen

Covington & Burling LLP
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T +1 202 662 5549 | eandersen@cov.com
www.cov.com

COVINGTON

From: Benson, Stephen P. [mailto:stephen.benson@kattenlaw.com]
Sent: Friday, September 29, 2017 3:44 PM
To: Andersen, Erica <eandersen@cov.com>; Beis, Kimberly A. <kimberly.beis@kattenlaw.com>; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com) <JBlumenfeld@mnat.com>; Noreika, Maryellen (MNoreika@mnat.com) <MNoreika@mnat.com>; Allergan-aczone <Allergan-aczone@cov.com>; Benson, Stephen P. <stephen.benson@kattenlaw.com>; Holub, Matthew M. <matthew.holub@kattenlaw.com>
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Dear Erica,

It was a pleasure speaking with you about the Protective Order.

On the meet and confer, we informed Allergan our position was the entire ANDA is Highly Confidential and Taro could not agree to a protective order that designated the ANDA as being Confidential and viewable to in-house counsel. That said, we repeated what we have offered in the first meet and confer regarding the OCA: in the event Allergan identifies those portions of the ANDA it believes are "critical", we will work with Allergan to designate those portions as Confidential under the protective order. We asked if those sections Allergan identified in its Sept. 22 correspondence were the sections Allergan would like designated as Confidential. Allergan would not say and repeated its all or nothing at all position. It appears Allergan is now willing to agree to the form of the protective order if Taro agrees "critical portions" of the ANDA can be designated as Confidential. If Allergan would identify those portions it views as "critical" we can work with our client to get you confirmation whether we would agree to designate all or some of those documents as Confidential. If those sections are the sections identified in your Sept. 22 correspondence, please let us know. We note our position on this has been consistent since we negotiated the OCA. Further, we have already told you we would agree to provide Allergan's in-house counsel with information regarding Taro's formulation once the Protective Order is in place, specifically the section we originally produced prior to producing

Taro's entire ANDA. Given Allergan has the burden to prove infringement, has the ANDA and should know what it views as "critical information", we are a bit confused as to why Allergan won't tell us what it wants.

Taro appreciates Allergan agreeing to the additional restrictions relating to patent office proceedings by in house counsel in the protective order. I don't believe we received an updated version of the protective order reflecting that agreement. Please forward that for our review.

As to expert access to those sections of the ANDA identified in your Sept. 22 correspondence, Taro is willing to agree to Allergan providing those documents to experts provided the procedures are followed from the draft Protective Order (for example we will need disclosure of the experts (if different from those in your Sept. 22 correspondence), executed Schedule A, etc.). Additionally, any experts must acknowledge once a protective order is entered they will not only be contractually bound to abide by those terms, but under court order to abide by the same terms. Please provide us the information pursuant to the terms of the draft protective order and we can provide the information to the client for review.

As to the Initial Disclosures, Allergan has been in possession of Taro's ANDA since before Allergan filed its complaint against TPI. As such, Allergan is in possession of far more information than it would normally have access to at this point in the litigation. Taro is investigating the person at Taro with the most knowledge, but given Allergan has information obtained through discovery, we do believe our disclosures not only satisfy the rules, but Allergan is in a far better position due to Taro's prompt disclosures and expeditious production of critical documents going to the heart of the present dispute.

Sincerely,

Stephen

STEPHEN P. BENSON
Partner
Katten Muchin Rosenman LLP
525 W. Monroe Street / Chicago, IL 60661-3693
p / (312) 902-5448 f / (312) 902-1061
stephen.benson@kattenlaw.com / www.kattenlaw.com

From: Andersen, Erica [mailto:eandersen@cov.com]
Sent: Thursday, September 28, 2017 12:02 PM
To: Beis, Kimberly A.; Benson, Stephen P.; jcp@pgmhlaw.com; dab@pgmhlaw.com
Cc: Blumenfeld, Jack (JBlumenfeld@mnat.com); Noreika, Maryellen (MNoreika@mnat.com); Allergan-aczone
Subject: RE: Allergan, Inc. v. Taro Pharmaceutical Industries Ltd. (D. Del. C.A. No. 17-663), and Allergan, Inc. v. Taro Pharmaceuticals, Inc. (D. Del. C.A. No. 17-1048)

Steven,

Thank you for speaking with us about the Protective Order and Initial Disclosures yesterday. With respect to the Protective Order, we are unable to agree to a form of order which does not guarantee in-house access to at least the critical portions of the ANDA. We explained that we are amenable to Taro identifying sections of the ANDA which Taro is comfortable (or uncomfortable) sharing with in-house counsel, and could potentially move forward with the Protective Order if Taro provides us with this information. You were not amenable to providing us with such a list. We also informed you that we could consider edits to the prosecution bar to make Taro more comfortable, and assured you that both outside and in-house counsel take their obligations under Protective Orders very seriously. You maintained your position that Taro's ANDA is highly confidential information, and that in-house counsel does not need access to all ANDA or formulation documents. Our understanding is that the parties are at an impasse, and need to follow the procedures set out in Paragraphs 2(j) and 3 of Judge's Fallon's Proposed Patent Scheduling Order (attached). Please confirm your understanding is the same, so that Delaware counsel may call to get a hearing date.

Given that the parties appear to have an agreement on expert access to confidential information, we also would like to renew our request of September 6 with respect to experts (see e-mail from J. Lou at 4:27 pm). We will follow the procedures set forth in Paragraphs 18 and 19 of the version of the Protective Order you sent to us at 5 pm on Monday, September 25. Please confirm immediately that Taro is amenable to this procedure for expert access.

With respect to Taro's Initial Disclosures, Taro has not named a single person from Taro "likely to have discoverable information that the disclosing party may use to support its claims or defenses." When we raised this issue, you told us that Taro was currently working to identify the person with the most knowledge as a corporate representative. You also informed us that Taro would respond to our Interrogatories and directed us to the ANDA, which contains the names of certain individuals. We stated we believe that Taro has an independent obligation to provide names in its Initial Disclosures in accordance with Rule 26. We continue to believe Taro's Initial Disclosures are inadequate, and that Taro should amend them promptly. Please confirm Taro will do so within 5 days. If not, please provide a time today or tomorrow for a meet-and-confer, so if needed we can raise both issues on our joint call to the Court.

Regards,
Erica

Erica N. Andersen

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COVINGTON

Exhibit D

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

ARTHROCARE CORPORATION, Plaintiff, vs. GYRUS MEDICAL, INC., GYRUS ENT, L.L.C., and GYRUS ACMI, INC., Defendants.	:	CIVIL ACTION
	:	NO. 07-729 (SLR)

- - -

Wilmington, Delaware
Wednesday, January 28, 2009
2:00 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, U.S.D.C.J.

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL
BY: JACK B. BLUMENFELD, ESQ.

-and-

WEIL, GOTSHAL & MANGES LLP
BY: CABRACH J. CONNOR, ESQ.
(Austin, Texas)

Counsel for Plaintiff

Valerie J. Gunning
Official Court Reporter

APPEARANCES (Continued):

POTTER, ANDERSON & CORROON
BY: DAVID E. MOORE, ESQ.

-and-

OLIFF & BERRIDGE, PLC
BY: DARLE M. SHORT, ESQ.
(Alexandria, Virginia)

Counsel for Defendants

- - -

during the course, no one really wants to take the time to make that determination now.

MR. SHORT: Well, there are two problems, your Honor. We don't know what we can tell our client. Okay? I mean, they have some oddball scientific theories, but we can't go to our client and tell them, because they designate the whole transcript confidential.

THE COURT: But you do have at least one person, one client representative?

MR. SHORT: No.

THE COURT: That's the problem. Everyone deserves one client representative who is entitled to look at all information because there's no way that litigation can go forward without that. So that is probably the better answer. And if you have not agreed to that, then you really ought to.

MR. SHORT: We tried, but we could not reach an agreement.

THE COURT: Because you couldn't find people?

MR. SHORT: Right. We proposed -- they proposed some on -- but we were actually here last July on this, your Honor.

THE COURT: And so that was never --

MR. SHORT: Resolved.

THE COURT: I'm sorry. I --

MR. BLUMENFELD: It was resolved by the parties, your Honor. We proposed someone. They proposed prosecution counsel. We said no. Both parties just said, forget it.

THE COURT: Yes. Well, is a better way basically -- well, I don't know which is better. To me, perhaps a better mechanism, to be able to share information with your client, if you really think the information should not be deemed confidential, is to say, is for you to identify the information you want to share, and if you can't get agreement from the parties, then I will get involved, because even if they say this is confidential and this isn't, it sound like you might disagree about that anyway.

MR. SHORT: Right. And also it kind of gives them your case strategy. If you say we want this section declassified, you are kind of giving up what you think is important.

Besides sharing it with the client, we don't know what we can give to the Court. They mark discussions of prior art highly confidential.

THE COURT: Well --

MR. SHORT: It's clearly not.

THE COURT: As I said, every brief and every appendix I get in every patent case is marked confidential, so that everything is filed under seal until we get to the point where there are filings made and you

Exhibit E

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

AUTOZONE INC., a Nevada corporation, and SPEEDBAR INC., a Nevada corporation, : CIVIL ACTION

Plaintiffs,

v.

TRI-STATE AUTO OUTLET, INC., a Delaware corporation, and ROBERT MOSEDER, a Delaware citizen, : NO. 04-103 (SLR)

Defendants.

- - -

Wilmington, Delaware
Tuesday, August 3, 2004 at 4:40 o'clock, p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, CHIEF JUDGE

- - -

APPEARANCES:

MONTGOMERY McCRACKEN WALKER & RHOADS
BY: RICHARD MONTGOMERY DONALDSON, ESQ.
-and-
SHAW PITTMAN, LLP
BY: ALAN S. COOPER, ESQ., and
ALISA KEY, ESQ.
(Washington, District of Columbia)

Counsel for Plaintiffs

MORRIS NICHOLS ARSHT & TUNNELL
BY: KAREN JACOBS LOUDEN, ESQ., and
JAMES W. PARRETT, JR., ESQ.

Counsel for Defendants

- oOo -

P R O C E E D I N G S

(Proceedings commenced at 4:40 p.m.)

THE COURT: Hi, counsel. Thanks for coming in. I didn't feel like making the attorneys clean up because we're not done with our suppression hearing yet, so I will be going back to that when we're done here.

I did get a letter about a couple of issues that you all want to address so why don't we begin. I don't know whose issues they are and what does it take. Who wants to take the lead?

MR. COOPER: The first one, the contention depositions relates to an objection that the defendants have interposed with respect to several paragraphs in a Rule 30(b)(6) notice of taking deposition of the corporate defendant. Defendants' counsel have been kind enough to provide us with copies of some transcripts of hearing before you, your Honor, and other judges dealing with contention discovery. However, I really don't believe that this is the type of contention discovery that was being addressed in what appeared to be the patent cases that were involved in those transcripts.

We're not asking a lay witness to explain the legal basis or the legal foundation or articulate what the contention means. What we're really trying to do is find out

what facts there are that support various defenses that the defendants have asserted. For example, their second defense is laches. One of the elements of laches that they have the burden of proving is that there is detrimental reliance or prejudicial reliance on whatever delay has occurred. Presumably, that is going to be proved at trial through the testimony of a witness. I think we're entitled to depose that witness.

THE COURT: Don't use that word. I don't like the word "entitled" because we're really entitled to very little in this life, despite what some of our politicians try to tell us.

MR. COOPER: It's from one of my daughters. But apart from that, it's our position we need to take the deposition to find out what that testimony is going to be at trial and that interrogatories really are not a satisfactory substitute. I'm not interested in what my learned adversary has to say about what the facts are. I want to find out what the witness is going to say. I want to have the ability to ask follow-up questions, to judge what the witness's credibility is going to be at trial. I think these are all legitimate areas for discovery and can't really be dismissed as contention discovery.

They've also asserted as a defense that there is no likelihood of confusion. It's not -- I mean that is

essentially an argument denial because we have the burden of proof on that but they have asserted that as a defense, and I think we're entitled to interrogate a witness about what facts support that defense. They have covered the same areas in their 30(b)(6) notice directed to us, to the plaintiffs.

THE COURT: Well, first of all, as a judge who has been on the bench for awhile, you get to the point where you lay out rules. You don't want to go back and completely have to reinvent the rule and draw the line again. So basically if you both agree to take contention depositions, that's fine. But generally, I don't believe that contention depositions are the way to go.

The way I think you need to go is to go through interrogatories, through which you find out who has these facts, and then you depose those people. They might in fact be the same people but I just don't believe that I want to be in the business of saying, yes, this is a good contention deposition or this is a bad contention deposition. I don't have the time for that.

So if you have asked what do you base your defense of laches on and who has the information, then, yes, you can go and ask that person what facts they know; but just to go in and say we want a 30(b)(6) deposition, I just won't allow it that way. So it's a matter of form but it makes a my life easier because I don't have of those arguments about

Page 9

THE COURT: Is there anything else about contention depositions?

MS. JACOBS LOUDEN: I believe that is it, your Honor.

THE COURT: The next thing on the agenda that I have is scheduling of depositions.

MS. JACOBS LOUDEN: Well, your Honor, we used well the time that you were in hearing to take a visit over to Judge Thynge's courtroom because the difficulty that we were having is we had a mediation date coming up and witnesses were unavailable. Fortunately, Judge Thynge was able, amazingly, to give us a date to resolve that issue.

THE COURT: That is amazing.

MS. JACOBS LOUDEN: So you can take that off, and we were able to resolve that on our own.

THE COURT: And the last issue, on the written agenda anyway, is entry of protective order.

MR. PARRETT: I'm happy to speak to that. My name is James Parrett. It's a pleasure to appear before you.

The issue we have with the protective order is essentially who can see the documents under the protective order. The plaintiffs proposed a two-tier protective order. We think it's only necessary to have a single-tier confidential protective order. Under the system the plaintiffs had

Page 10

proposed, their in-house counsel would have access to all the information under both tiers of confidentiality but our client wouldn't be able to get access to that information.

Our client is a single proprietor of a car dealership and he just doesn't have any in-house counsel to satisfy that. But we think it's important that our client have access to information so he can provide them with meaningful litigation advice. He is the only person who can make these litigation decisions. He is the person that has to make the call on whether to settle or go forward with the litigation. And to be able to do that, we have to be able to speak with him frankly and realistically about what is going on with the case.

We understand they have some concerns over the sensitivity of the information and we don't think there is any competitive concerns here. Our client is a car dealer. The plaintiffs sell auto parts. We think they're not competitors to each other. Moreover, our clients agree to be bound by the protective order. So we think it's a fair and necessary that our client have access to the information so he can make real decisions about the case.

THE COURT: What kind of information are we talking about?

MR. COOPER: We're talking about information that is commercially very sensitive, market research, that

Page 11

typically in my experience is not disclosed to nonattorneys for the adversary. We're also talking about settlement agreements in prior litigation where those agreements on their face provide that the existence and the terms of the agreement is to be maintained in confidence.

I just don't see how, why it is necessary for non-attorneys to have access to that information. The in-house counsel for the plaintiffs function in a legal capacity. They're part of the attorney's team working on the case, they're not in a management role, and this type of two-tiered approach is what we have typically used in a number of cases without any difficulty.

THE COURT: Right. I think the problem is you are dealing with someone who doesn't have any representative of the company because it's always been our court's practice to allow someone from the company to have access. Otherwise, the client who is responsible for making ultimately the decision of where to go doesn't have the information he or she or it needs to make those important decisions.

So we start with the principle that someone from the company needs to have access to almost all the information. Otherwise, the lawyers are running the show and I don't think that is a good idea. So the question is whether, rather than drawing a line at the personnel involved, whether we can pick out the most critical sensitive documents

Page 12

and decide whether that is one of those, whether that is the kind of information the client needs to know to make the kind of decisions they're going to make. I think that is really the question. And it could be we have to make it on a document-by-document basis rather than taking out the categories. I don't know. Settlement agreements, they're important for what purpose? It's always nice to know what other people settle for to see whether you can play or not.

MR. COOPER: The principal concern I have is the settlement agreements impose an obligation to maintain it in confidence. And I don't want to --

THE COURT: Right. License agreements are different than settlement agreements, and I'm not confident I'm sure why settlement agreements are going to be shown to anybody, let alone a client. Why are settlement agreements going to be shown as opposed to the ultimate business license that is the result of the settlement agreements?

MR. PARRETT: As far as we understand, the settlement agreements are the ultimate business license in the case. That is dispositive of the case.

MR. COOPER: See, there is no license aspect to these settlement agreements.

MR. PARRETT: Right. As far as I understand, it's prior litigations, and litigations have been done away because of the settlement agreements. I think it's important our

Exhibit F

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., :
:
Plaintiff, : No. 1:17-cv-663-VAC-SRF
:
v. :
:
TARO PHARMACEUTICALS, :
INC., et al., :
Defendants. :

Wednesday, September 20, 2017
11:00 a.m.

Rule 16 Conference
Courtroom of Judge Sherry R. Fallon

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE Sherry R. Fallon,
United States District Court Magistrate

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
BY: MARYELLEN NOREIKA, ESQ.

-and-

COVINGTON & BURLING
BY: CHANSON CHANG, ESQ.
BY: ERICA ANDERSON, ESQ.

On behalf of Plaintiff

APPEARANCES CONTINUED:

PHILLIPS, GOLDMAN, McLAUGHLIN & HALL,
P.A.
BY: JOHN PHILLIPS, ESQ.

-and-

KATTEN MUCHIN ROSENMAN LLP
BY: STEPHEN BENSON, ESQ.

On behalf of Defendants

THE COURT: Good morning. This is the time set aside to enter a case scheduling order in Allergan vs. Taro Pharmaceuticals, et al. Let's begin with the introduction of counsel starting with Plaintiff. Ms. Noreika?

MS. NOREIKA: Good morning, Your Honor. Mary Noreika from Morris Nichols for Plaintiff. With me at counsel table are Chanson Chang and Erica Anderson from Covington & Burling in D.C.

MR. CHANG: Good morning, Your Honor.

MS. ANDERSON: Good morning, Your Honor.

THE COURT: Good morning. Mr. Phillips?

MR. PHILLIPS: Good morning, Your Honor. Jack Phillips on behalf of Taro. With me in the courtroom is Stephen Benson of Katten Muchin Rosenman from Chicago.

THE COURT: Very good. Thank you. Welcome, everyone. I took a look at the scheduling order, and you're a small group so don't feel that you need to stand at the lectern

when you speak. This is going to be more of an informal session than is normally conducted at these scheduling conferences for a number of reasons.

I looked at the proposed scheduling order including some areas where the parties are not in complete agreement, and what struck me with regard to the parties' joint proposal for a proposed trial in May of 2019 is that when you add in the length of time for post-trial briefing and then you look at that in comparison to the expiration of the 30-month stay in this case that's shown on the docket to be October 18, 2019, you're not leaving the judge much time to get a decision issued. It's a very condensed time frame.

As all of you know with the unique circumstances that our District Court is facing these days with the judicial vacancies and the wonderful group of visiting judges who are truly helping us out at this time, it's difficult for -- we don't have an assigned judge now, so I can't tell you which judge will be your ultimately trial judge and what that judge's

adequate time for back and forth.

THE COURT: Two weeks is reasonable. That's fine if it works for Defendants. I will look for that in two weeks. We will do an internal calendar note to follow up on.

All right. With that, I think that concludes our conference today. If any other matters crop up along the way during this process and you think it will be helpful to reconvene in Part 2 of our Rule 16 process, we can do that. It doesn't necessarily have to be in person. We can do it by teleconference, if needed. My thought was whatever I get from you in two weeks is probably something I will be able to enter without further discussion.

MR. BENSON: If I may, one other issue with respect to the protective order. Just to highlight this so it's on your radar, I expect that there may be disagreement about access to inhouse counsel for the ANDA.

To be clear, we produced the entire ANDA before the answer was due, actually before the second suit was filed against Taro,

Inc. So they have been in possession of the entire ANDA for quite some time. The issue is Allergan is currently prosecuting a number of patent applications in the Patent Office, and we have a fairly significant concern of giving our entire ANDA to Allergan's inhouse counsel in that context, and that is what has been delaying things.

Certainly, with respect to getting the ANDA to their experts if they think that's necessary, we are amenable to that, but I think there's going to be an issue with the protective order just with respect to access for inhouse counsel. We have represented before with respect to the basic formulation that we have produced, separately carved it out, that we don't object to inhouse counsel having access to that portion of that ANDA, but it's the entire ANDA, that's our concern, although we will work with Plaintiffs and try to get that on file.

I know we represented by the 30th and we hope to still be able to make that date. It is possible that when that particular order is submitted, that there may be disputed issues.

THE COURT: Well, have your set time, think about time for meaningful conferences to meet and confer on that point. And if there are any issues, then it may be time to start looking at dates for a teleconference on how we can work this out in terms of who has access to the materials.

I can tell you that there's not going to be any time in early -- October is getting tight for me to hear this issue. But perhaps if you ask to push it later in the day like 4 o'clock or 4:30, it may be something that we can discuss at that time. I don't want this to delay. It's like a domino effect. If I get hung up on a protective order and it takes time to get that resolved, then that's more delay in terms of getting documents exchanged and depositions, et cetera. So try to work that out. Get a date as early as you can, and I will confer behind the scenes with Ms. Hicks on trying to find some time to carve out for this case if there's an issue with the protective order that needs to be resolved.

MR. BENSON: Thank you, Your

Honor.

MR. CHANG: Your Honor, if I may briefly respond?

THE COURT: Sure.

MR. CHANG: I think this underscores the problem here in that this is the first we're hearing from Defendants' counsel about any of the issues that they see and any of the issues and areas where they feel comfortable sharing the ANDA. That's not a proposal that has been shared with us. We have been asking for six weeks for a response. And what we have offered already in the protective order is limited access to two individuals, and I believe there is a prosecution bar already in the draft order. So to the extent that they have these issues, they sat on it for six weeks before raising it here for the first time at this hearing.

THE COURT: I hear you and I will try to look at the positive aspects, that if it took a Rule 16 inperson conference to get this discussion opened, then that has been the benefit of it. And all of you have now heard me

and my views and how I want to manage the litigation, so hopefully that will be a note of inspiration to try and work these issues out, but I will deal with it if need be with the protective order and I will find time in my schedule even though it's very busy in October to do that as promptly as I can.

MR. CHANG: Thank you, Your Honor.

THE COURT: All right. Thank you, counsel. Have a good day.

(The proceedings ended at 11:40 a.m.)

C E R T I F I C A T I O N

I, Taneha Carroll, Professional Court Reporter, certify that the foregoing is a true and accurate transcript of the foregoing proceeding.

I further certify that I am neither attorney nor counsel for, nor related to nor employed by any of the parties to the action in which this proceeding was taken; further, that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action.

/s/Taneha Carroll
Taneha Carroll

Professional Reporter and Notary Public

Exhibit G

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERZ PHARMACEUTICALS, LLC, and MERZ NORTH AMERICA, INC.,

Plaintiffs,

v.

TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICAL INDUSTRIES LTD.,

Defendants.

Civil Action No.: 15-cv-3720-WHP-SN

STIPULATED PROTECTIVE ORDER

Whereas discovery in this action may necessarily involve the disclosure of certain documents, things and information (including electronically stored information) in the possession, custody or control of a party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure or contain information involving privacy interests of individuals; and

Whereas the parties have in good faith conferred and have agreed upon the terms of a Protective Order and for good cause shown; therefore

The parties stipulate, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, subject to the approval of the Court, to the following Protective Order:

1. Scope of Protection.

1.1 This Protective Order shall govern any record of information, designated pursuant to ¶ 3 of this Protective Order, produced in this action, including, without limitation, all designated deposition testimony, all designated testimony taken at a hearing or other proceeding,

all designated interrogatory answers, documents and other discovery materials, whether produced informally or in response to interrogatories, requests for admissions, requests for production of documents or other formal methods of discovery.

1.2 This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any federal procedural rule or Southern District of New York local rule, and any supplementary disclosures thereto.

1.3 This Protective Order shall apply to the parties and any non-party from whom discovery may be sought and who desires the protection of this Protective Order.

2. Definitions.

2.1 As used herein, the terms "CONFIDENTIAL" and "CONFIDENTIAL INFORMATION" (which are used herein interchangeably and are synonymous with one another) mean (i) any form of trade secret or other confidential research, development, or commercial information within the meaning of Fed. R. Civ. P. 26(c)(1)(G), or (ii) information involving privacy interests of one or more individuals. The designation of "CONFIDENTIAL" or "CONFIDENTIAL INFORMATION" by a producing party constitutes its representation that it reasonably and in good faith believes that the designated material constitutes or contains information in one or more of the foregoing categories.

3. Designation.

Each party shall have the right to designate information as CONFIDENTIAL, subject to this Protective Order. To the extent that material is marked CONFIDENTIAL, such material shall only be revealed to or used by limited categories of individuals, as provided for herein, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts,

summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed CONFIDENTIAL, and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

4. Marked Documents and Things.

4.1 Each page of a document and each thing that constitutes or contains CONFIDENTIAL INFORMATION shall be labeled or marked with the legend "CONFIDENTIAL" or "CONFIDENTIAL INFORMATION" when the document or thing is produced to the receiving parties. Anything that cannot be so labeled or marked on its face shall be labeled or marked by placing the appropriate legend on a container or package in which it is produced or on a tag attached thereto. Material produced without any such legend shall not be subject to the protections afforded such information under this Protective Order unless otherwise agreed by the Parties, ordered by the Court, or designated in accordance with ¶ 17 of this Protective Order.

4.2 Should a party opt to make materials available for inspection in response to a discovery request, such inspection shall be conducted on an outside-counsel-eyes-only basis. Once produced, such materials shall be treated by the receiving parties in accordance with any confidentiality designation made at the time of their production.

4.3 Documents and things produced or made available for inspection may be subject to redaction, in good faith by the producing party, of information that is neither relevant to the subject of this litigation nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege or to work-product immunity. Each such redaction, regardless of size, shall be clearly labeled. This paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information. All documents redacted

based on attorney-client privilege or work-product immunity shall be listed on a privilege log in accordance with Federal Rule of Civil Procedure 26(b)(5).

4.4 Documents produced prior to entry of this Protective Order will be treated as having been produced marked "CONFIDENTIAL." If a Producing Party decides that the previously produced documents do not require this heightened level of confidentiality, then that Producing Party shall provide the Receiving Party with the Bates range(s) of the previously produced documents and the appropriate confidentiality designations.

5. Limit On Use And Disclosure Of Designated Information.

5.1 Each party and all persons bound by the terms of this Protective Order shall use any information or document designated CONFIDENTIAL only in connection with the prosecution or defense of this action, except by consent of the parties or order of the Court. Such use includes, but is not limited to, offering evidence and testimony at trial and/or other hearings, preparing for and conducting discovery, preparing for trial, and supporting or opposing any motion in this action. Except as provided for in this Order, no party or other person shall disclose or release any information or document governed by this Protective Order to any person not authorized pursuant to this Protective Order to receive such information or document.

Material designated CONFIDENTIAL, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the receiving parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by the receiving parties for any purpose other than in connection with this action, including without limitation for any research, development, manufacture, patent prosecution, financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case).

Absent consent of the producing parties and/or further order of this Court, all persons receiving information designated CONFIDENTIAL are expressly prohibited from using or disclosing such information in connection with any practice before or communication with the United States Patent and Trademark Office, the FDA, the United States Pharmacopoeia, or their counterpart organizations in any other jurisdiction.

If a party opts to produce documents containing CONFIDENTIAL INFORMATION in hard copy, then any complete hard copy production sets shall be maintained at the offices of outside counsel only. Nothing in this Protective Order requires that individual documents containing CONFIDENTIAL INFORMATION be maintained at the offices of outside counsel.

5.2 It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated CONFIDENTIAL INFORMATION received by the party, provided that such rendering of advice and opinions shall not reveal the content of such information, other than in summary form, except by prior written agreement with counsel for the producing party.

5.3 The attorneys of record for the parties and other persons receiving information governed by this Protective Order shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons.

5.4 The parties agree to meet and confer in good faith prior to trial to establish procedures concerning the use of CONFIDENTIAL INFORMATION at trial. Nothing in this Protective Order shall preclude any party from moving the Court to seal the courtroom, trial exhibits, or the trial transcript in order to preserve the confidential nature of any CONFIDENTIAL INFORMATION used at trial.

6. Disclosure Of Designated Information.

Except as provided in ¶¶ 12, 13, and 19, documents or information designated CONFIDENTIAL INFORMATION, as described in this Protective Order, shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

(a) one (1) in-house counsel for each party, including their authorized secretarial, paralegal, clerical and legal assistant staff whose duties require access to material designated CONFIDENTIAL INFORMATION;

(i) for Plaintiffs, the designated person shall be Pamela Butler;

(ii) for Defendants, the designated person shall be Kathryn Jones;

(iii) designated individuals pursuant to ¶ 6(a) are not and will not be: (1) for the duration of three years after the conclusion of the litigation including appeals involved in prosecution of patent applications (including both foreign and U.S. applications) or in any drafting or amendment of claims or claim language in any patent office proceeding, including but not limited to post grant proceedings such as *inter partes* reviews, *ex parte* reexaminations, and post grant review proceedings, or in advising regarding the drafting, filing, or prosecution of patent applications (including both foreign and U.S. applications) in any patent office proceeding, including but not limited to post grant proceedings such as *inter partes* reviews, *ex parte* reexaminations, and post grant review proceedings, relating to any gel compositions for topical administration that contain naftifine or salts thereof; (2) for the duration of one year after the conclusion of the litigation including appeals involved in the preparation of any portion of any FDA communications relating to the standards for review, approval, or marketing of any gel compositions for topical administration that contain naftifine or salts thereof, including

FDA petitioning activity, if such communications relate to any party's products in addition to or other than the products of the party or its licensees, by whom the designated individual is employed; or (3) for the duration of three years after the conclusion of the litigation including appeals involved in competitive business decision making with respect to any gel compositions for topical administration that contain naftifine or salts thereof;

(iv) in the event that any of the designated individuals cease to have responsibilities relating to this litigation, a party may designate another individual to replace the previously designated individual upon giving written notice of such change to the opposing party or parties pursuant to ¶ 6(a)(v);

(v) if any party desires to disclose information designated CONFIDENTIAL to a person designated pursuant to ¶ 6(a)(iv) above, it must first identify in writing (which can be by email) to the attorneys for the opposing party such person desired to be designated pursuant to ¶ 6(a)(iv); such written identification shall include a description of the cause and reasons for making the substitution and a description of the newly identified person's responsibilities within the receiving party's organization. If the party has a good faith basis for believing it would be harmed by the proposed disclosure, the attorney for the opposing party shall have five (5) business days from receipt of such notice to object in writing (which can be by email) to disclosure of such information to the person designated pursuant to ¶ 6(a)(iv) so identified. Objections must be in writing and state with particularity the basis for the objection. In the event of such an objection to a person designated pursuant to ¶ 6(a)(iv), the parties shall meet and confer within three (3) business days to attempt to resolve the concerns giving rise to the objection. If

the parties are unable to reach an agreement, the party objecting to disclosure may, within five (5) business days of the meet and confer, request that the Court issue an order barring such disclosure. The objecting party shall have the burden of showing why that person should not have access to CONFIDENTIAL INFORMATION. Pending resolution of any such motion or application, no disclosure of CONFIDENTIAL INFORMATION shall be made to that person. Any party that fails to object in writing within five (5) business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 6(a);

(vi) prior to disclosure of CONFIDENTIAL INFORMATION to any designated individual pursuant to ¶ 6(a), counsel for the receiving part shall first obtain from the designated individual pursuant to ¶ 6(a) and serve upon the disclosing party an executed Confidentiality Undertaking (in the form set forth in Exhibit A hereto) prior to disclosing any CONFIDENTIAL INFORMATION to the designated individual pursuant to ¶ 6(a);

(b) outside trial counsel or outside attorneys of record for the parties, including, but not limited to, such attorneys' partners, associates, staff and contract attorneys, and their secretarial, paralegal, clerical and legal assistant staff whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION;

(c) the Court and Court personnel, as provided in ¶ 14;

(d) outside consultants or experts retained by the parties and their staffs or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 7, and who first execute the written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) prior

to receiving any CONFIDENTIAL INFORMATION to be bound by the terms of this Protective Order;

(e) court reporters, videographers, employed in connection with this action and their respective staffs;

(f) non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, and other litigation support personnel (*e.g.*, graphic designers and animators, database entry personnel); and

(g) any interpreter or translation service retained to assist outside counsel of record, and any typist or transcriber used thereby.

7. Identification Of Experts.

7.1 If any party desires to disclose information designated CONFIDENTIAL to any expert or consultant pursuant to ¶ 6(d) above, it must first identify in writing (which can be by email) to the attorneys for the producing party each such expert or consultant. The attorney for the producing party shall have five (5) business days from receipt of such notice to object in writing (which can be by email) to disclosure of such information to any of the experts or consultants so identified. Any party that fails to object in writing within five (5) business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 6(d). No CONFIDENTIAL INFORMATION may be disclosed to any proposed expert or consultant until such time as the parties have agreed or are deemed to have agreed upon disclosure to the expert for purposes of ¶ 6(d) pursuant to the provisions of ¶¶ 7.1 or 7.2.

7.2 The identification of an expert or consultant pursuant to ¶ 7.1 shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-

date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical industry within the last five (5) years (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26 or where the fact of the engagement itself is protected from disclosure by a confidentiality agreement), including a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last four years. The parties shall attempt to resolve any objections informally. If the objections cannot be resolved, the party opposing disclosure of the CONFIDENTIAL INFORMATION to the expert or consultant may raise the issue with the Court in accordance with the Court's procedures for resolution of discovery disputes. If the issue is raised with the Court, the party opposing disclosure shall bear the burden of proof with respect to the propriety of its objection and blocking of said individual from serving as an expert or consultant in this case. Any party that fails to raise such an issue with the Court within ten (10) business days of notifying a party of an objection to disclosure under ¶ 7.1 shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 6(d).

8. Agreement Of Confidentiality.

In no event shall any information designated CONFIDENTIAL be disclosed to any person authorized pursuant to ¶ 6(d) until such person has executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) acknowledging and agreeing to be bound by the terms of this Protective Order. Counsel for the party seeking to disclose material designated under this Order to any such person pursuant to this paragraph shall be responsible for retaining the executed originals of all such Confidentiality Undertakings.

Any vendor described in ¶ 6(f) who is accessing hard copies of CONFIDENTIAL

INFORMATION on behalf of a party shall return to the party's counsel all hard copies of such documents as soon as the information has been encoded and loaded into the computer, copied, prepared or otherwise processed by the vendor.

Any vendor providing a party with on-going access to electronic copies of CONFIDENTIAL INFORMATION shall provide limited and secure access to the information (such as information stored on a computer) and the vendor will guarantee to provide access (*e.g.*, through access codes or passwords) only to people who are entitled to access it under this Protective Order (including people retained or employed by the vendor entitled to such access).

9. Related Documents.

The restrictions contained herein to the use of information designated CONFIDENTIAL INFORMATION shall apply to (a) portions of documents, copies, extracts, and complete or partial summaries prepared from or containing such information; (b) portions of deposition transcripts and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (c) portions of briefs, memoranda or any other papers filed with the Court and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (d) deposition testimony designated in accordance with ¶ 10; and/or (e) testimony taken at a hearing or other proceeding that is designated in accordance with ¶ 11.

10. Designation Of Deposition Transcripts.

10.1 Portions of deposition transcripts containing CONFIDENTIAL INFORMATION may be designated as subject to this Protective Order either on the record during the deposition or by providing written notice within thirty-five (35) days following receipt of the official transcripts of the deposition to the reporter and all counsel of record of the specific pages and

lines that contain CONFIDENTIAL INFORMATION, in which case all counsel receiving such notice shall mark the copies or portions of the designated transcript in their possession or under their control as directed by the designating party.

10.2 All deposition transcripts not previously designated shall be deemed to be, and shall be treated as CONFIDENTIAL for a period of thirty-five (35) days after receipt of the official transcript of the deposition, and the transcript shall not be disclosed during such time by a non-designating party to persons other than those persons qualified to receive such information pursuant to this Protective Order.

10.3 The designating party shall have the right to exclude from portions of a deposition, before the taking of testimony which the designating party designates CONFIDENTIAL and subject to this Protective Order, all persons other than those persons previously qualified to receive such information pursuant to this Protective Order. If such individuals fail to comply with such a request, the requesting counsel for the producing party may seek relief from the Court pursuant to the Court's procedures for resolution of discovery disputes, and pending resolution of that request, instruct or request the witness not to answer questions relating to, or to limit disclosure of, the CONFIDENTIAL INFORMATION at issue.

11. Designation Of Hearing Testimony Or Argument.

With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL INFORMATION, counsel may designate on the record prior to such disclosure that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL INFORMATION is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the

hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

12. Disclosure to Other Individuals.

Notwithstanding any other provision of this Protective Order, CONFIDENTIAL INFORMATION may be disclosed to the following persons, irrespective of whether they are identified in ¶ 6, as follows:

12.1 CONFIDENTIAL INFORMATION may be disclosed to persons not identified in ¶ 6 as agreed by the producing parties.

12.2 Any receiving party may move the Court (in accordance with the Court's procedures for resolution of discovery disputes) for an Order that a person not identified in ¶ 6 be given access to information designated CONFIDENTIAL. If the motion is granted, such person may have access to the CONFIDENTIAL INFORMATION after first signing the Confidentiality Undertaking set forth in Exhibit A.

12.3 Nothing in this Protective Order shall prohibit counsel or a party from disclosing a document containing information designated CONFIDENTIAL at deposition, at trial, or at any other court hearing, to: (i) any person who appears from the face of the document to have drafted, prepared, executed, had knowledge of the substance of, or received the document, or any person who is reasonably likely to have had prior lawful access to the document or the information contained therein; or (ii) a currently employed officer, employee, Rule 30(b)(6) designee, or expert of the party that produced the CONFIDENTIAL INFORMATION..

13. Confidentiality Of Party's Own Documents and Information.

Nothing herein shall affect the right of the designating party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own

information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the designating party the information becomes public knowledge. Similarly, the Protective Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

14. Designation Of Documents Under Seal.

Any information designated CONFIDENTIAL, if filed with the Court, shall be filed with a motion for leave to file under seal pursuant to the presiding Judge's Individual Practices—such as section V of the Individual Practices of Judge William H. Pauley, III, the Local Rules, and shall comply with section 6 of the Electronic Case Filing Rules and Instructions for the Southern District of New York. Material filed under seal shall be made available only to the Court and to persons authorized by the terms of this Protective Order.

Other than in the case of *ex parte in camera* filings, any document filed electronically under seal must be served upon opposing counsel by electronic means on the same day the sealed document is filed with the Court.

A redacted version of the sealed documents shall be filed electronically within ten (10) business days of the filing of the sealed document. Within three (3) business days of filing a sealed document, the party filing the sealed document shall contact outside counsel for any party whose CONFIDENTIAL INFORMATION is contained within the document filed under seal to determine what information needs to be redacted for the redacted version to be filed with the Court, and shall propose redactions to said outside counsel.

Any party to this litigation and any interested member of the public can challenge the redaction or sealing of materials filed with the Court. In the event that any person challenges the propriety of a document being filed under seal, the Party who designated the material as CONFIDENTIAL shall be allowed to oppose any such challenge.

15. Other Protections.

15.1 No person shall use any CONFIDENTIAL INFORMATION, or information derived therefrom, for purposes other than the prosecution or defense of this action.

15.2 Any party may mark any document or thing containing CONFIDENTIAL INFORMATION as an exhibit to a deposition, hearing or other proceeding, provided the witness at such proceeding is qualified under the terms of this Protective Order to have access to such designated material.

16. Challenge to Confidentiality.

16.1 This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from (a) claiming that any matter designated hereunder is not entitled to the protections of this Protective Order, (b) applying to the Court for an Order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order, or (c) applying for a further Order modifying this Protective Order in any respect. No party shall be obligated to challenge the propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation.

16.2 On any challenge to the designation of any information, the burden of proof shall lie with the producing party to establish that the information is, in fact, CONFIDENTIAL

INFORMATION. If a party seeks declassification or removal of particular items from this designation on the ground that such designation is not necessary to protect the interests of the designating party, the following procedure shall be utilized:

(a) The party seeking such declassification or removal shall give counsel of record for the other party written notice thereof, specifying the designated information as to which such removal is sought and the reasons for the request and including sufficient information to identify documents containing the information as to which removal is sought, such information to include at least beginning and ending Bates numbers and any other available identifying information; and

(b) If, after conferring, the parties cannot reach agreement concerning the matter within seven (7) business days after the delivery and receipt of the notice, then the party requesting the declassification or removal of particular items may challenge the designation in accordance with the procedures for resolution of discovery disputes.

17. Inadvertent Failure To Designate.

A producing party or non-party that inadvertently fails to designate as CONFIDENTIAL an item pursuant to this Protective Order at the time of production may thereafter make a designation pursuant to this Protective Order by serving notice thereof in writing, accompanied by substitute copies of each item, appropriately designated as CONFIDENTIAL. Upon receipt of such notice and properly marked material, the receiving parties shall treat such information consistent with the redesignation. All copies of the misdesignated documents shall be promptly destroyed or returned to the producing party, and any memoranda or work product derived therefrom shall thereafter be treated as containing CONFIDENTIAL INFORMATION.

Should any CONFIDENTIAL INFORMATION be disclosed, through inadvertence or otherwise, by the receiving party to any person or party not authorized under this Protective Order, then the receiving party shall (a) use its best efforts to obtain the return of any such material or information and to bind such person to the terms of this Protective Order; (b) within three (3) business days of the discovery of such disclosure, inform such person of all provisions of this Protective Order and request such person to sign the Confidentiality Undertaking in the form attached hereto as Exhibit A; and (c) within five (5) business days of the discovery of such disclosure, inform the producing party of all pertinent facts relating to such disclosure, including the identity of such person and the information disclosed.

18. Inadvertent Production or Disclosure of Privileged Materials.

Pursuant to Federal Rule of Evidence 502, the inadvertent production or disclosure of any document or thing (including information) otherwise protected by the attorney-client privilege, work-product immunity, or other privilege or immunity shall not operate as a waiver of any such privilege or immunity if, after recognizing that privileged information has been produced or disclosed, the party who made the inadvertent production or disclosure sends to each receiving party a written request for return of the inadvertently produced or disclosed document or thing within a reasonably prompt period of time after recognizing that the privileged information has been produced or disclosed. Within ten (10) days of receiving such a request, the receiving party shall (a) return to the producing party all such documents and things identified by the producing party as being protected by the attorney-client privilege, work-product immunity, or other privilege or immunity and as having been inadvertently produced (or at the option of the receiving party destroy the original with written verification provided to outside counsel for the producing party), and (b) delete any electronic records thereof (with the exception of back-up

tapes or other archival media, which should be treated in accordance with standard retention policies). The receiving party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information, except as provided in subparagraph (a) below.

(a) If the receiving party wishes to contest that any such document or thing is protected by the attorney-client privilege or by work-product immunity, the receiving party shall so notify the producing party in writing when the document or thing is returned to the producing party ("Notice of Designation"). The receiving party may retain one (1) copy of the document(s) or thing(s) at issue for the purposes of filing a motion to contest the designation. The copy retained by the receiving party must be sequestered, and may not be used for any purpose except to present the information to the Court for a determination of the claim of privilege.

(b) Within five (5) days after receiving a Notice of Designation, the producing party shall provide to the receiving party for each such document or thing a description of the basis for the claim of privilege or immunity.

(c) Within five (5) days after receiving such description, the receiving party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the Court's procedures for resolution of discovery disputes. If a motion to contest the designation is not filed within such five (5)-day period, the one (1) copy, if any, retained by the receiving party as set forth in ¶ 18(a) shall be immediately returned to the producing party or, at the option of the Receiving Party, destroyed. Likewise, in the event that the Court rejects the receiving party's challenge to the privileged status of the inadvertent production, the one (1) copy, if any, retained by the receiving party as set forth in

¶ 18(a) shall be immediately returned to the producing party or, at the option of the Receiving Party, destroyed.

(d) With respect to documents and things subsequently generated by a receiving party, which documents and things contain information derived from such inadvertently produced documents and things, if the receiving party does not notify the producing party that the receiving party disputes the claims of attorney-client privilege or work-product immunity, or if the Court rejects any challenge by the receiving party to the privileged status of the inadvertent production, the receiving party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

(e) The procedures set forth in this ¶ 18 for challenging the privileged status of an inadvertent production shall not result in any waiver of the attorney-client privilege, the work product immunity, or any other privilege or immunity.

19. Prior or Public Knowledge.

This Protective Order shall not apply to information that is or was available to the public prior to disclosure. The restrictions contained in this Protective Order shall not apply to information that is or was available to the public other than by an act or omission of the party to whom such disclosure is made, or that is legitimately and independently acquired from a source not subject to this Protective Order.

20. Limitation Of Protective Order.

This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work-product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate

under the Federal Rules of Civil Procedure or the Local Rules of the Southern District of New York.

21. Other Proceedings.

Any person or party subject to this order who may be subject to a subpoena, motion or court order in another case to disclose information that is designated by another party in this case as CONFIDENTIAL in this case shall promptly notify that other party of the subpoena, motion or court order so that it may have an opportunity to appear and be heard on whether such information should be disclosed.

22. Non-Party Material.

The terms of this Protective Order, as well as the terms of any protective order that may be entered into between a discovering party and third party for the production of information to the discovering party, are applicable to CONFIDENTIAL INFORMATION provided by a non-party. Information provided by a non-party in connection with this action and designated CONFIDENTIAL, pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

23. Final Termination of this Litigation.

Within ninety (90) days following final termination of this litigation, including all appeals therefrom, unless otherwise agreed to in writing by an attorney of record for the designating party, each party shall assemble and return, or destroy and certify destruction of, all materials containing information designated CONFIDENTIAL, including all copies—either electronic or hard copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that a party is not obligated to return or destroy CONFIDENTIAL INFORMATION that may be contained on electronic backup back-up tapes or other archival

media, which should be treated in accordance with standard retention policies. Notwithstanding the foregoing, and subject to a continuing obligation to protect all such material pursuant to this order, outside counsel may retain any archive copies of any filings, court papers, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work-product (regardless of whether such materials contain or reference CONFIDENTIAL INFORMATION for archival records).

24. Waiver Or Termination Of Order.

No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court.

The termination of employment of any person with access to any CONFIDENTIAL INFORMATION shall not relieve such person from the obligation of maintaining the confidentiality of such information.

25. Modification Of Order; Prior Agreements.

This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

26. Section Captions.

The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

27. **Days.**

All references to "days" in this Order shall be construed as calendar days, unless otherwise specifically indicated.

28. **Order Applicable Upon Filing with the Court.**

Upon filing this Protective Order with the Court, the Parties agree to treat it as "So Ordered," subject to any future modifications by agreement of the Parties or by the Court.

Dated: November 9, 2015

Jointly submitted,

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Counsel for Defendants Taro Pharmaceuticals U.S.A. Inc. and Taro Pharmaceutical Industries Ltd.

IT IS SO ORDERED this ___ day of _____, 201__.

11-12-15

The Honorable William H. Pauley III
United States District Court Judge

tnr

EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERZ PHARMACEUTICALS, LLC, and MERZ NORTH AMERICA, INC., Plaintiffs, v. TARO PHARMACEUTICALS U.S.A., INC. and TARO PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No.: 15-cv-3720-WHP-SN

DECLARATION AND CONFIDENTIALITY UNDERTAKING

I certify that I have received and carefully read the Stipulated Protective Order in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of that Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court, Southern District of New York, for any proceedings involving the enforcement of that Order. I declare under penalty of perjury under the laws of the United States of America this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this _____day of _____, _____.

_____
Name

_____
Signature

_____
Present Employer or Other Business Affiliation

_____
Business Address

Exhibit H

13/756,392	TOPICAL COMPOSITIONS AND METHODS FOR MAKING AND USING SAME	P51403	10-31-2017::16:20:08

Bibliographic Data

Application Number:	13/756,392	Correspondence Address Customer Number:	7055
Filing or 371 (c) Date:	01-31-2013	Status:	Patented Case
Application Type:	Utility	Status Date:	06-25-2014
Examiner Name:	ALLEY, GENEVIEVE S	Location:	ELECTRONIC
Group Art Unit:	1617	Location Date:	-
Confirmation Number:	5734	Earliest Publication No:	US 2014-0213658 A1
Attorney Docket Number:	P51403	Earliest Publication Date:	07-31-2014
Class / Subclass:	424/400	Patent Number:	8,778,365
First Named Inventor:	Bhushan Hardas , Summerville, NC (US)	Issue Date of Patent:	07-15-2014
First named Applicant:	MERZ PHARMACEUTICALS, LLC , Greensboro, NC (US)	International Registration Number (Hague):	-
Entity Status:	Small	International Registration Publication Date:	-
AIA (First Inventor to File):	No		

Title of Invention:	TOPICAL COMPOSITIONS AND METHODS FOR MAKING AND USING SAME

Close Window

13/756,392	TOPICAL COMPOSITIONS AND METHODS FOR MAKING AND USING SAME	P51403	10-31-2017::16:10:56

Parent Continuity Data

Description	Parent Number	Parent Filing or 371(c) Date	AIA(First Inventor to File)	Parent Status	Patent Number
No Parent Continuity Data Found.					

Child Continuity Data

13/941,201 filed on 07-12-2013 which is Patented claims the benefit of 13/756,392
14/764,545 filed on 07-29-2015 which is Patented claims the benefit of 13/756,392
14/974,502 filed on 12-18-2015 which is Patented claims the benefit of 13/756,392
15/255,464 filed on 09-02-2016 which is Pending claims the benefit of 13/756,392
PCT/US14/14098 filed on 01-31-2014 which is Published claims the benefit of 13/756,392
14/297,293 filed on 06-05-2014 which is Patented claims the benefit of 13/756,392
14/857,232 filed on 09-17-2015 which is Pending claims the benefit of 13/756,392

Close Window

Exhibit I

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MERZ PHARMACEUTICALS, LLC and MERZ NORTH AMERICA, INC., Plaintiffs, v. TARO PHARMACEUTICALS U.S.A., INC. AND TARO PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 15 CV 3720 JUDGE PAULEY

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merz Pharmaceuticals, LLC and Merz North America, Inc. (collectively, "Merz") by way of Complaint against Defendants Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceutical Industries Ltd. (collectively, "Taro") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Taro's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market a generic version of Merz's innovative NAFTIN® (Naftifine HCl) Gel 2% product ("NAFTIN® 2% Gel") prior to the expiration of United States Patent Number 8,778,365.

THE PARTIES

2. Plaintiff Merz Pharmaceuticals, LLC is a limited liability corporation organized and existing under the laws of North Carolina, with a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615.

3. Plaintiff Merz North America, Inc. is a corporation organized and existing under the laws of North Carolina, with a principal place of business at 6501 Six Forks Road, Raleigh, North Carolina 27615.

4. Upon information and belief, defendant Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") is a corporation organized and existing under the laws of New York having a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

5. Upon information and belief, defendant Taro Pharmaceutical Industries, Ltd ("Taro Industries") is a corporation organized and existing under the laws of Israel, having a place of business at 14 Hakitor Street, Haifa Bay, Israel 26110.

JURISDICTION AND VENUE

6. Upon information and belief, Taro USA is in the business of, *inter alia*, developing, manufacturing, marketing, promoting, selling, distributing, and/or obtaining regulatory approval for generic copies of innovative, branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

7. Upon information and belief, Taro Industries is in the business of, *inter alia*, developing, manufacturing, marketing, selling, distributing, and/or obtaining regulatory approval for generic copies of innovative, branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries, including, at least, Taro USA.

8. Shares of Taro Industries are listed on the New York Stock Exchange under the symbol TARO.

9. Upon information and belief, defendant Taro USA is a wholly-owned subsidiary of Taro Industries.

10. Upon information and belief, defendant Taro USA acts at the direction of, control of, and for the benefit of Taro Industries and is controlled and/or dominated by Taro Industries.

11. Upon information and belief, employees of defendant Taro USA and defendant Taro Industries act in concert and in some instances individuals are simultaneously employees of Taro USA and Taro Industries.

12. Upon information and belief, the Interim Chief Financial Officer, Group Vice President, and Chief Accounting Officer of Taro Industries is Mr. Michael H. Kalb, CPA of New York. Upon information and belief, Mr. Michael H. Kalb is also the Chief Financial Officer of Taro USA.

13. Upon information and belief, Taro Industries employs at least one person in the State of New York.

14. Upon information and belief, Taro Industries has dominion and control over the regulatory and financial affairs of Taro USA. Upon information and belief, Taro Industries is responsible for preparing, filing, and reporting regulatory documents with United States regulatory agencies, including the United States Securities and Exchange Commission ("SEC"). Upon information and belief, Taro Industries directly files documents with the SEC in the care of Taro USA. Taro Industries lists Mr. Michael H. Kalb as a contact person for Taro Industries on regulatory submissions filed with the SEC. The contact address provided is a New York address.

15. Taro Industries, in required regulatory filings with the SEC, reports Food and Drug Administration ANDA filings without distinction as to whether Taro USA or Taro Industries is the ANDA holder. Upon information and belief, in a letter accompanying a Form 6-K filing filed with the SEC on or about February 10, 2015, Taro Industries states that they have 30 ANDAs awaiting approval. Upon information and belief, ANDA Number 208201 ("the Taro ANDA"), the ANDA related to this action, is one of the 30 ANDAs described in Taro Industries' Form 6-K filing.

16. Upon information and belief, Taro USA and Taro Industries participated and collaborated in the research and development, and/or the preparation and filing, of the Taro ANDA, continue to participate and collaborate in seeking FDA approval of that application, and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the generic products described in the Taro ANDA throughout the United States, including within this judicial district, in the event the FDA approves the Taro ANDA.

17. Upon information and belief, defendant Taro USA is registered with the New York Department of State as a Domestic Business Corporation having Identification Number 185681 and has appointed an agent to receive service of process within the State of New York.

18. Upon information and belief, Taro USA and Taro Industries derive substantial revenue from its sales of pharmaceutical products within the State of New York. For instance, Taro USA and/or Taro Industries have numerous reimbursed products listed in the New York State Department of Health Medicaid system.

19. Taro USA and Taro Industries have availed themselves of the rights, benefits and privileges of this Court by filing at least one complaint in the Southern District of New York:

Taro Pharmaceuticals Industries, Ltd. and Taro Pharmaceuticals U.S.A., Inc. v. Sun Pharmaceutical Industries, Ltd., et al., Civil Action No. 1:09-cv-08262-PGG.

20. Taro USA and Taro Industries have admitted to, consented to or have not contested, the jurisdiction of this Court in at least one prior Southern District of New York action: *Shire LLC v. Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc.*, Civil Action No. 1:10-cv-05631-PGG.

21. Upon information and belief, this Court has personal jurisdiction over defendant Taro USA because, *inter alia*, Taro USA is incorporated in New York, conducts business in New York, has purposefully availed itself of the rights and benefits of the laws of the State of New York and has a principal place of business in this Judicial District.

22. Upon information and belief, at least as a result of the contacts described above, this Court has personal jurisdiction over defendant Taro Industries.

23. This action arises under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281.

24. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a).

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

REGULATORY REQUIREMENTS FOR NEW AND GENERIC DRUGS

26. A party wishing to market a new drug that has not previously been approved by the FDA—an innovative or pioneering drug—must file a New Drug Application ("NDA") with the FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

27. To demonstrate that an innovative drug is safe and effective, an NDA applicant, typically, is required to perform a series of clinical trials incurring considerable costs in the process.

28. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an ANDA for a generic version of that drug. 21 U.S.C. § 355(j)(2)(A)(iv).

29. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data and, instead, may include bioavailability, bioequivalence, and/or information from studies on the proposed generic drug. 21 U.S.C. § 355(j).

30. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

THE APPROVED DRUG PRODUCT - MERZ'S NAFTIN® 2% GEL

31. Merz Pharmaceuticals, LLC and Merz North America, Inc. are pharmaceutical companies in the business of, *inter alia*, researching, developing, manufacturing, marketing, promoting, selling, distributing, and/or obtaining regulatory approval for innovative pharmaceutical products throughout the United States, including within this judicial district. Merz Pharmaceuticals, LLC researched, developed, applied for, and obtained FDA approval to manufacture, sell, promote, and/or market Merz's NAFTIN® 2% Gel products in the United States, including in this jurisdiction, and in the process expended considerable resources.

32. Merz Pharmaceuticals, LLC is the owner of Food and Drug Administration approved New Drug Application Number 204286 for NAFTIN® 2% Gel ("the NAFTIN® 2% Gel NDA").

33. The FDA approved the NAFTIN® 2% Gel NDA on June 27, 2013.

34. NAFTIN® 2% Gel, as approved in the NAFTIN® 2% Gel NDA, is currently marketed and sold throughout the United States, including in the State of New York, by and/or on behalf-of Merz under the trade name NAFTIN® (Naftifine HCl) Gel 2%.

35. NAFTIN® 2% Gel is an allylamine antifungal and is currently indicated for the treatment of interdigital tinea pedis caused by the organisms *Trichophyton rubrum, Trichophyton mentagrophytes, and Epidermophyton floccosum* in patients eighteen (18) years of age and older.

36. Claims of the '365 patent cover NAFTIN® 2% Gel.

THE PATENT-IN-SUIT

37. On July 15, 2014, the United States Patent and Trademark Office ("USPTO") duly and legally issued United States Patent Number 8,778,365 entitled "Topical Compositions and Methods for Making and Using Same" ("the '365 patent").

38. Bhushan Hardas, M.D. and Donna Dalton are the named inventors of the '365 patent and assigned their rights to Merz Pharmaceuticals, LLC.

39. Merz Pharmaceuticals, LLC is currently the sole assignee and owner of all right, title, and interest in and to the '365 patent.

40. Merz North America, Inc. is currently the exclusive licensee of the'365 patent.

41. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '365 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for NAFTIN® 2% Gel.

42. The '365 patent discloses and claims, *inter alia*, gel compositions that include naftifine or pharmaceutically acceptable salts thereof. Naftifine hydrochloride is a pharmaceutically acceptable salt of naftifine.

43. The '365 patent is valid and enforceable and will expire no earlier than January 31, 2033.

44. A true and correct copy of the '365 patent is attached hereto as Exhibit A.

TARO'S INFRINGING ANDA SUBMISSION

45. Upon information and belief, Taro submitted Abbreviated New Drug Application Number 208201 ("the Taro ANDA") to the FDA pursuant to 21 U.S.C. § 355(j) and Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to make, use, offer to sell, and/or sell in and import into the United States naftifine hydrochloride 2% gel ("the Taro Product").

46. Upon information and belief, the Taro ANDA refers to and relies upon the NAFTIN® 2% Gel NDA and contains data that, according to Taro, demonstrates the bioequivalence of the Taro Product and NAFTIN® 2% Gel.

47. Upon information and belief, the Taro ANDA seeks approval to engage in the commercial manufacture, use, import, or sale of the Taro Product before the expiration of the '365 patent.

48. Upon information and belief, Taro had actual and/or constructive knowledge of the '365 patent prior to and/or during the process of submitting the Taro ANDA and/or seeking approval to market a generic NAFTIN® 2% Gel and/or prior to taking actions in preparation for submitting the Taro ANDA.

49. By letter dated April 1, 2015 ("Notice Letter"), Taro USA notified Merz that it had filed the Taro ANDA, along with a Paragraph IV Certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), seeking approval to market Taro's Product prior to the expiration of the '365 patent.

50. On May 4, 2015, pursuant to an Offer of Confidential Access, Merz's counsel received portions of the ANDA filed by Taro, and Merz's counsel reviewed those portions of the ANDA.

51. This action is commenced before the expiration of forty-five days from the date of Merz's receipt of the Notice Letter.

COUNT 1

INFRINGEMENT OF THE '365 PATENT UNDER 35 U.S.C. § 271

52. Paragraphs 1–51 of this Complaint are realleged and incorporated herein by reference.

53. At least under 35 U.S.C. § 271(e)(2), Taro's submission to the FDA of the Taro ANDA seeking approval to manufacture, use, import, offer to sell, and/or sell the Taro Product, along with a Paragraph IV Certification related thereto prior to the expiration of the '365 patent, constitutes an act of infringement of one or more claims of the '365 patent.

54. If approved, the commercial manufacture, use, offer to sell, sale, or importation of the Taro Product would infringe one or more claims of the '365 patent.

55. Taro would, through the manufacture, use, import, offer for sale, and/or sale of the Taro Product directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '365 patent.

56. Taro was aware of the '365 patent when engaging in these knowing and purposeful activities and was aware that filing the Taro ANDA with a Paragraph IV certification with respect to the '365 patent constituted an act of infringement of the '365 patent.

57. Upon information and belief, the Taro Product contains the same active ingredient that is used in Merz's NAFTIN® 2% Gel.

58. Upon information and belief, the Taro Product contains the same active ingredient that is claimed in the '365 patent.

59. Upon information and belief, the Taro Product is intended to be a generic version that is the same, or substantially the same, as the NAFTIN® 2% Gel.

60. The Taro Product is covered by one or more claims of the '365 patent.

61. Upon information and belief, Taro, under 35 U.S.C. § 271(b) or other applicable law, acted in concert, actively supported, participated in, encouraged, and/or induced infringement of one or more claims of the '365 patent.

62. Upon information and belief, Taro plans and intends to, and will, actively induce infringement of the '365 patent when the Taro ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval of the Taro ANDA.

63. Upon information and belief, Taro knows that the naftifine hydrochloride 2% gel product described in the Taro ANDA is especially made or adapted for use in infringing the '365 patent and is not suitable for substantial non-infringing uses.

64. Upon information and belief, Taro plans and intends to, and will, contribute to the infringement of the '365 patent when the Taro ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval of the Taro ANDA.

65. If infringement of the '365 patent by Taro is not enjoined, Merz will suffer substantial and irreparable harm for which there is no adequate remedy at law

66. The foregoing actions by Taro constitute and/or would constitute infringement of the '365 patent under 35 U.S.C. § 271(a), (b), (c) and/or (e) or other applicable law.

PRAYER FOR RELIEF

WHEREFORE, Merz respectfully requests that the Court enter judgment in its favor and against Taro on the patent infringement claims set forth above and respectfully requests that this Court:

a. enter judgment that Taro has infringed one or more claims of the '365 patent through Taro's submission of ANDA Number 208201 to the FDA seeking approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Taro Product before the expiration of the '365 patent;

b. enter judgment that the '365 patent is valid and enforceable;

c. order, pursuant to 35 U.S.C. § 271(e)(4)(A) or other applicable law, that the effective date of any approval by the FDA of ANDA Number 208201 be a date that is not earlier than the expiration of the '365 patent or such later date as the Court may determine;

d. permanently enjoin, pursuant to 35 U.S.C. § 271(e)(4)(B) or other applicable law, Taro and all persons acting in concert with Taro from any commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States, of the Taro Product, or any product or compound which infringes the '365 patent;

e. enjoin Taro and all persons acting in concert with Taro from any commercial manufacture, use, marketing, distributing, offers to sell, sale, or importing within the United States, or importation into the United States, of the Taro Product, or any product or compound which infringes the '365 patent, until expiration of the '365 patent or such later date as the Court may determine;

f. enjoin Taro and all persons acting in concert with Taro from seeking, obtaining, or maintaining approval of the Taro ANDA until expiration of the '365 patent or such later date as the Court may determine;

g. enjoin Taro and all persons acting in concert with Taro from seeking, obtaining, or maintaining regulatory approval to commercially manufacture, use, offer to sell, or sell within the United States, generic naftifine hydrochloride gel products that would infringe the '365 patent until expiration of the '365 patent or such later date as the Court may determine;

h. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271 and award Merz costs, expenses, and disbursements in this action, as well as reasonable attorneys' fees; and

i. award Merz such further and additional relief as this Court deems just and proper.

Respectfully submitted,

Date: May 14, 2015

By:_____

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ATTORNEYS FOR PLAINTIFFS
MERZ PHARMACEUTICALS, LLC and
MERZ NORTH AMERICA, INC.

EXHIBIT A


US008778365B1

(12) **United States Patent**
Hardas et al.

(10) **Patent No.: US 8,778,365 B1**
(45) **Date of Patent: Jul. 15, 2014**

(54) **TOPICAL COMPOSITIONS AND METHODS FOR MAKING AND USING SAME**

(71) Applicant: **Merz Pharmaceuticals, LLC**, Greensboro, NC (US)

(72) Inventors: **Bhushan Hardas**, Summerville, NC (US); **Donna Dalton**, High Point, NC (US)

(73) Assignee: **Merz Pharmaceuticals, LLC**, Greensboro, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/756,392**

(22) Filed: **Jan. 31, 2013**

(51) **Int. Cl.**

A61K 9/00	(2006.01)
A61K 9/14	(2006.01)
A61K 31/74	(2006.01)
A01N 25/32	(2006.01)
A61K 47/38	(2006.01)

(52) **U.S. Cl.**
CPC ***A61K 47/38*** (2013.01)
USPC **424/400**; 424/406; 424/484; 424/78.07

(58) **Field of Classification Search**
CPC A61K 9/06; A61K 8/042
USPC 424/400, 406, 484, 78.07
See application file for complete search history.

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(57) **ABSTRACT**

The present invention relates to improved topical gel compositions comprising an active agent, and uses thereof.

17 Claims, 2 Drawing Sheets

Figure 1

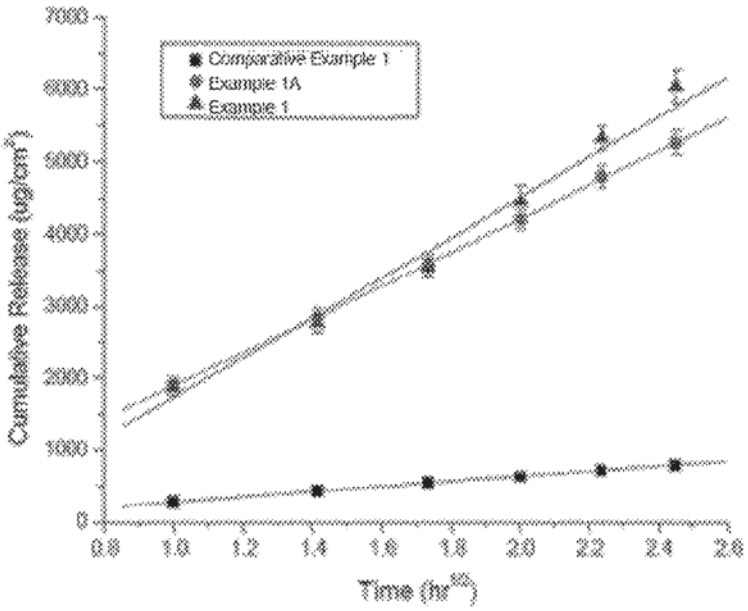
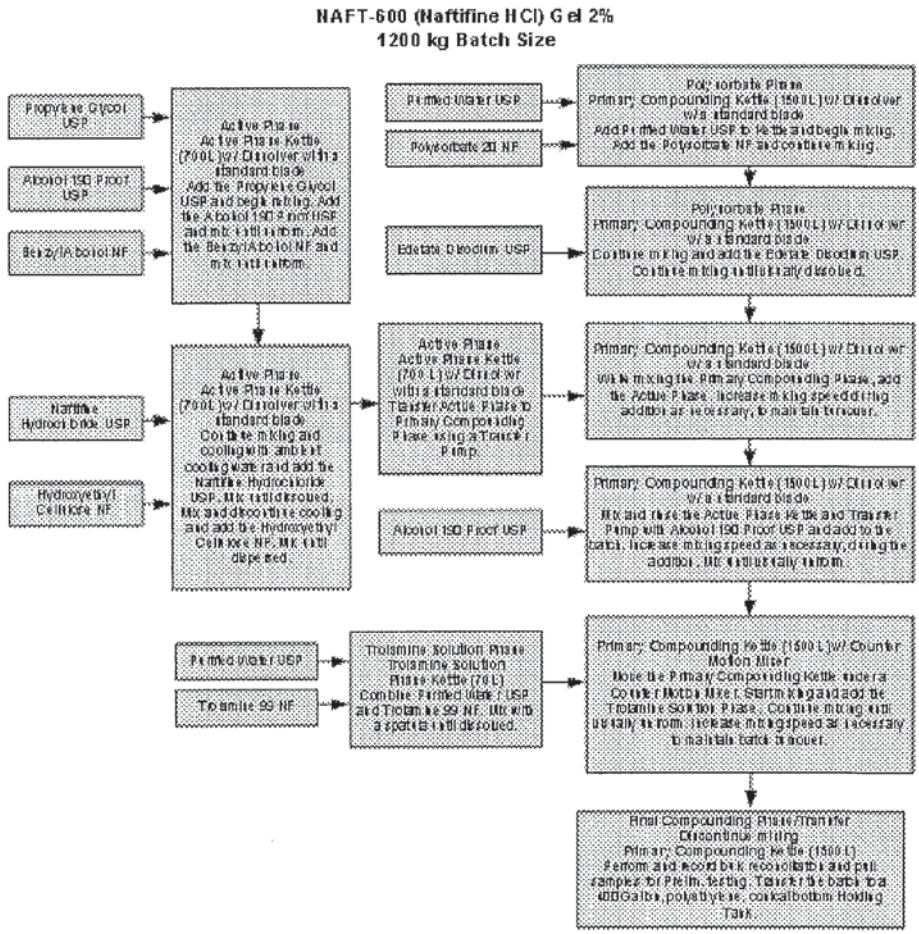

Comparative Example 1
Example 1A
Example 1
Cumulative Release (ng/cm²)
Time (hr^0.5)
0
1000
2000
3000
4000
5000
6000
7000
0.8
1.0
1.2
1.4
1.6
1.8
2.0
2.2
2.4
2.6

Figure 2


NAFT-600 (Naftifine HCl) Gel 2%
1200 kg Batch Size
Propylene Glycol USP
Alcohol 190 Proof USP
Benz/Alcohol NF
Active Phase
Active Phase Kettle (700L) w/ Dimolver with a standard blade
Add the Propylene Glycol USP and begin mixing. Add the Alcohol 190 Proof USP and mix until uniform. Add the Benz/Alcohol NF and mix until uniform.
Naftifine Hydrochloride USP
Hydroxyethyl Cellulose NF
Active Phase
Active Phase Kettle (700L) w/ Dimolver with a standard blade
Continue mixing and cooling with ambient cooling water and add the Naftifine Hydrochloride USP. Mix until dissolved. Mix and discontinue cooling and add the Hydroxyethyl Cellulose NF. Mix until dispersed.
Active Phase
Active Phase Kettle (700 L) w/ Dimolver with a standard blade
Transfer Active Phase to Primary Compounding Phase using a Transfer Pump
Purified Water USP
Trolamine 99 NF
Trolamine Solution Phase
Trolamine Solution Phase Kettle (70 L)
Combine Purified Water USP and Trolamine 99 NF. Mix with a spatula until dissolved.
Purified Water USP
Polysorbate 20 NF
Polysorbate Phase
Primary Compounding Kettle (1500 L) w/ Dimolver w/a standard blade
Add Purified Water USP to kettle and begin mixing. Add the Polysorbate NF and continue mixing.
Edetate Disodium USP
Polysorbate Phase
Primary Compounding Kettle (1500 L) w/ Dimolver w/a standard blade
Continue mixing and add the Edetate Disodium USP. Continue mixing until fully dissolved.
Primary Compounding Kettle (1500 L) w/ Dimolver w/a standard blade
With mixing the Primary Compounding Phase, add the Active Phase. Increase mixing speed/tilting addition as necessary, to maintain turnover.
Alcohol 190 Proof USP
Primary Compounding Kettle (1500 L) w/ Dimolver w/a standard blade
Mix and raise the Active Phase Kettle and Transfer Pump with Alcohol 190 Proof USP and add to the batch. Increase mixing speed as necessary, during the addition. Mix until uniform.
Primary Compounding Kettle (1500 L) w/ Counter Motion Mixer
Rinse the Primary Compounding Kettle with a Counter Motion Mixer. Start mixing and add the Trolamine Solution Phase. Continue mixing until uniform. Increase mixing speed as necessary to maintain batch turnover.
Final Compounding Phase/Transfer
Discontinue mixing
Primary Compounding Kettle (1500 L)
Perform and record bulk reconciliation and pull samples for Prelim. testing. Transfer the batch to a 400 Gallon, polyethylene, conical bottom Holding Tank.

TOPICAL COMPOSITIONS AND METHODS FOR MAKING AND USING SAME

FIELD

The present subject matter relates to improved topical pharmaceutical compositions comprising an active agent, and methods of making and using same to treat, ameliorate, or prevent a condition.

BACKGROUND

Topical compositions may be used to deliver an active agent for the treatment of various conditions and diseases. Formulating topical compositions presents several challenges. For example, it may be difficult to formulate topical compositions that will cause less irritation upon application of the same as compared to other topical compositions comprising the same active agent or active agents. In addition, it may also be difficult to prepare storage stable topical compositions that cause little or no irritation. Accordingly, there remains a need to develop more effective topical treatments.

SUMMARY

The present invention provides an improved gel composition for topical treatment. Provided formulations comprise an active agent, as described in detail herein. Methods of utilizing a provided formulation are described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graphical representation of the results obtained from a release assay in vitro test.

FIG. **2** is a flow chart illustrating a representative process for manufacturing provided gel compositions.

DETAILED DESCRIPTION OF THE INVENTION

As described above, there remains a need for improved topical gel compositions that are significantly more effective than known topical antifungal pharmaceutical compositions. The present invention provides gel compositions with surprisingly improved delivery of an active agent, which improved delivery allows for less frequent dosing and/or a shorter course of treatment. In some embodiments, compositions described herein dramatically reduce irritation or stinging associated with existing formulations. Further, in some embodiments, presently described gel compositions are effective for treating, inter alia, moccasin-type *Tinea pedis*, which was, heretofore, generally only effectively treated by an oral antifungal medication.

Gel Compositions:

In some embodiments, gel compositions of the present invention are comprised of:

(i) a first solvent;

(ii) optionally a second solvent;

(iii) a non-carbomer rheology modifier;

(iv) an active agent;

(v) optionally one or more solubizing agents; and

optionally one or more of: a diluent, a preservative, a pH adjuster, a chelating agent, a coloring agent, and a fragrance. Exemplary such gel compositions are described in further detail below and herein.

In some embodiments, the present invention provides a gel composition, wherein the composition does not comprise a carbomer.

In some embodiments, the present invention provides a gel composition, wherein the gel composition is a water soluble gel composition. In some embodiments, the present invention provides a gel composition, wherein the gel composition is not a water soluble gel composition.

In some embodiments, a provided gel composition has a viscosity or average viscosity of from about 30,000 to about 100,000 Centipoise ("cP"); from about 40,000 to about 90,000 cP; from about 50,000 to about 80,000 cP; from about 55,000 to about 75,000 cP; from about 55,000 to about 70,000 cP; from about 60,000 to about 70,000 cP; or from about 60,000 to about 66,000 cP.

In some embodiments, a provided gel composition has a viscosity or average viscosity of from about 55,000 to about 70,000 centipoise (cP).

In some embodiments, a provided gel composition has a viscosity or average viscosity of from about 30,000 to about 100,000 centipoise (cP).

Definitions:

As used herein, the terms "administer," "administering," and "administration," refer to any method which, in sound medical practice, delivers a provided composition, or an active agent contained therein, to a subject in such a manner as to provide a therapeutic effect.

The phrase "candidal onychomycosis" as used herein refers to a fungal yeast infection of the fingernails and/or toenails caused by a *Candida* spp., including for example, *Candida albicans* and *Candida parapsilosis*.

The term "carbomer" as used herein refers to a polymer of acrylic acid cross-linked with a polyfunctional compound, hence, a poly (acrylic acid) or polyacrylate.

The term "chelating agent" as used herein refers to any known pharmaceutically acceptable chelating agents. Suitable chelating agents can include but are not limited to any one or more of ethylenediaminetetraacetic acid(EDTA) and derivatives thereof, ethylene glycol-bis-(2-aminoethyl)-N,N,N',N'-tetraacetic acid (EGTA) and derivatives thereof, cyclohexanediamine tetraacetic acid (CDTA) and derivatives thereof, hydroxyethylethylenediamine triacetic acid (HEDTA) and derivatives thereof, diethylenetriamine pentaacetic acid (DTPA) and derivatives thereof, dimercaptopropane sulfonic acid (DMPS) and derivatives thereof, dimercaptosuccinic acid (DMSA) and derivatives thereof, aminotrimethylene phosphonic acid (ATPA) and derivatives thereof, N,N-bis(carboxymethyl)glycine (NTA) and derivatives thereof, nitrilotriacetic acid and derivatives thereof, citric acid and derivatives thereof, niacinamide and derivatives thereof, sodium desoxycholate and derivatives thereof, polyphosphates; porphine; and any pharmaceutically acceptable salts thereof.

As used herein, the term "dermatomycosis" refers to a fungal infection of the skin caused by a dermatophyte.

As used herein, the term "diluent" refers to water or saline.

As used herein, the phrases an "effective amount" or a "therapeutically effective amount" of an active agent or ingredient, or pharmaceutically active agent or ingredient, refer to an amount of the pharmaceutically active agent sufficient enough to have a therapeutic effect upon administration. Effective amounts of the pharmaceutically active agent will vary with the kind of pharmaceutically active agent chosen, the particular condition or conditions being treated, the severity of the condition, the duration of the treatment, the specific components of the composition being used, and like factors. For example, the presently described compositions can be topically applied in an amount sufficient to cover an affected area plus a margin of healthy skin or tissue surrounding the

affected area, for example, a margin of about 0.5 inches, at a frequency, for example, of once a day, for a time period, for example of about two weeks.

As used herein, the phrase "fungal infection" refers to any superficial fungal infection, including for example, one or more of a superficial fungal infection of the skin, onychomycosis, and a fungal infection of a hair follicle, each of which is as defined herein. Such fungal infections can include superficial fungal infections of the skin, including for example, one or more of *Tinea cruris, Tinea corporis*, interdigital *Tinea pedis*, moccasin-type *Tinea pedis, Tinea manuum, Tinea versicolor* (pityriasis), *Tinea nigra*, cutaneous candidiasis, *Tinea faciei*, and white and black piedra; fungal infections of the hair follicle including one or more of *Tinea capitis, Tinea Favose* (favus), and *Tinea barbae*; and onychomycosis, a fungal infection of one or more of the nail bed, matrix, and nail plate, caused by, for example, dermatophytes, yeasts, and non-dermatophyte molds.

As used herein, the phrase "fungal infection of the hair follicle" refers to a fungal infection of at least the tubular infolding of the epidermis (skin) containing the root of a hair of any one or more of the scalp, eyebrows, eyelashes, and bearded area of an individual. The phrase "fungal infection of the hair follicle" also refers to a fungal infection of the tubular infolding of the epidermis (skin) containing the root of a hair of any one or more of the scalp, eyebrows, eyelashes, and bearded area, along with a fungal infection of the hair shaft, of an individual. Such fungal infections can include, for example, one or more of *Tinea capitis, Tinea favosa*, and *Tinea Barbae*. The term "hair follicle" refers to a tubular infolding of the epidermis (skin) containing the root of a hair. The follicle is lined by cells derived from the epidermal layer of the skin. *Tinea capitis* (or severe highly-inflammatory cases sometimes termed Kerion) is a superficial fungal infection (dermatophytosis) of the skin of the scalp, eyebrows, and eyelashes, that attacks the hair follicles and shaft. The disease is primarily caused by dermatophytes in the *Trichophyton* and *Microsporum* genera, including for example, *Microsporum audouini, Microsporum canis, Microsporum distortum, Microsporum gypseum, Trichophyton megninii, Trichophyton mentagrophytes, Trichophyton rubrum, Trichophyton schoenleinii, Trichophyton tonsurans*, and *Trichophyton verrucosum*. The clinical presentation is typically a single or multiple patches of hair loss, sometimes with a 'black dot' pattern (often with broken-off hairs), that may be accompanied by inflammation, scaling, pustules, and itching. *Tinea favosa* can be considered a variety of *Tinea capitis* because it involves the scalp; however, it may also involve glabrous skin and nails. *Tinea favosa* is primarily caused by dermatophytes in the *Trichophyton* and *Microsporum* genera, including for example, *Microsporum gypseum* and *Trichophyton schoenleinii. Tinea barbae* is a superficial dermatophytosis that is limited to the bearded areas of the face, neck, chin, cheeks, and/or lips and occurs almost exclusively in older adolescent and adult males. The clinical presentation of *Tinea barbae* includes inflammatory, deep, kerion-like plaques and non-inflammatory superficial patches resembling *Tinea corporis* or bacterial folliculitis. The mechanism that causes *Tinea barbae* is similar to that of *Tinea capitis*, and is frequently the result of a *Trichophyton rubrum* (*T. rubrum*) infection but may also be the result of *Trichophyton mentagrophytes* var *granulosum* and *Trichophyton verrucosum*. Finally *Microsporum canis* and *Trichophyton mentagrophytes* var *erinacei* have been known to cause *Tinea barbae* but are relatively rare.

As used herein, the term "infection" refers to the invasion, development and/or multiplication of a microorganism within or on another organism. An infection may be localized to a specific region of an organism or systemic.

The phrase "non-carbomer rheology modifier/thickener" as used herein refers to any known rheology modifier/thickener that is not a carbomer. Suitable non-carbomer rheology modifiers/thickeners can include but are not limited to hydroxy celluloses, semi-synthetic polymers including carboxymethyl cellulose and starch; natural polysaccharides including but not limited to guar gum, locust bean gum, xanthan, chitosan and alginate. Suitable hydroxy celluloses include hydroxyethyl cellulose (HEC), hydroxymethyl cellulose (HMC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), and hydroxyethylmethyl cellulose (HEMC).

The phrase "non-irritating," as used herein, refers to the presently described topical pharmaceutical compositions, including for example, the presently described gel topical pharmaceutical compositions, that elicit reduced irritation, for example, reduced burning and/or stinging, in a subject, for example, as compared to the irritation elicited by known topical pharmaceutical compositions. For example, less than 5% of subjects treated with the presently described topical pharmaceutical composition report irritation due to application of the pharmaceutical composition, i.e., burning and/or stinging; less than 4% of subjects treated with the presently described topical pharmaceutical composition report irritation due to application of the pharmaceutical composition; less than 3% of subjects treated with the presently described topical pharmaceutical composition report irritation due to application of the pharmaceutical composition; less than 2% of subjects treated with the presently described topical pharmaceutical composition report irritation due to application of the pharmaceutical composition; or less than 1% of subjects treated with the presently described topical pharmaceutical composition report irritation due to application of the pharmaceutical composition. See the Examples and comparative Examples described herein. As used herein the term "pH adjuster" refers to any pharmaceutically acceptable composition, compound, or agent, suitable for adjusting the pH of the presently described topical pharmaceutical compositions without negatively affecting any property thereof. Suitable pH adjusters can include any pharmaceutically acceptable acid or base. Suitable pH adjusters can include but are not limited to hydrochloric acid, sulfuric acid, citric acid, acetic acid, formic acid, phosphoric acid, tartric acid, trolamine, sodium hydroxide and potassium hydroxide.

The phrase "occlusive dressing or covering" as used herein refers to any porous or non-porous dressing or covering that may retain moisture and/or heat, and/or may increase the concentration and/or absorption of the active agent being topically applied. Suitable occlusive coverings can include, for example, a bandage, wrap, coban-type dressings, silicone-type bandages, foam bandages, duct tape, plastic wrap, latex, rubber, or other non-permeable material, a commercially available adhesive bandage, gauze, a patch, an adhesive patch, a sock, and/or a glove or mitten.

The term "onychomycosis" as used herein refers to a fungal infection of the nail bed, matrix, and/or or nail plate. Onychomycosis is caused by three main classes of fungi: dermatophytes, yeasts (candidal onychomycosis), and non-dermatophyte molds. Dermatophytes are the most common cause of onychomycosis. Onychomycosis caused by non-dermatophyte molds is becoming more common worldwide. Onychomycosis due to *Candida* is less common. Dermatophytes that can cause onychomycosis include one or more of *Trichophyton rubrum, Trichophyton interdigitale, Epidermophyton floccosum, Trichophyton violaceum, Microsporum*

gypseum, Trichophyton tonsurans, Trichophyton soudanense, and *Trichophyton verrucosum*, and such disease is often also referred to as *Tinea ungium. Candidal onychomycosis* include cutaneous candidisis and mucocutaneous candidiasis, that are caused by one or more *Candida* species, including for example, *Candida albicans* and *Candida parapsilosis*. Non-dermatophyte molds that can cause onychomycosis can include one or more of, for example, *Scopulariopsis brevicaulis, Fusarium* spp., *Aspergillus* spp., *Alternaria, Acremonium, Scytalidinum dimidiatum*, and *Scytalidinium hyalinum*. There are four classic types of onychomycosis including the following: distal and lateral subungal onychomycosis (DLSO) that is the most common form of onychomycosis, and is usually caused by *Trichophyton rubrum* and/or *Trichophyton interdigitale*, which invades the nail bed and the underside of the nail plate; white superficial onychomycosis (WSO) is caused by fungal (e.g., *T. mentagrophytes*) invasion of the superficial layers of the nail plate to form "white islands" on the plate, non-dermatophyte molds cause deep white superficial onychomycosis; proximal subungal onychomycosis (PSO) is fungal penetration of the newly formed nail plate through the proximal nail fold and it is the least common form of onychomycosis in healthy people, but is found more commonly when the patient is immunocompromised; endonyx onychomycosis (EO), and candidal onychomycosis (CO) which is *Candida* species invasion of the fingernails.

As used herein, the phrase "pharmaceutically acceptable salts" refers to salts of certain ingredient(s) which possess the same activity as the unmodified compound(s) and which are neither biologically nor otherwise undesirable. A salt can be formed with, for example, organic or inorganic acids. Such suitable acids include acetic acid, acetylsalicylic acid, adipic acid, alginic acid, ascorbic acid, aspartic acid, benzoic acid, benzenesulfonic acid, bisulfic acid, boric acid, butyric acid, camphoric acid, camphorsulfonic acid, carbonic acid, citric acid, cyclopentanepropionic acid, digluconic acid, dodecylsulfic acid, ethanesulfonic acid, formic acid, fumaric acid, glyceric acid, glycerophosphoric acid, glycine, glucoheptanoic acid, gluconic acid, glutamic acid, glutaric acid, glycolic acid, hemisulfic acid, heptanoic acid, hexanoic acid, hippuric acid, hydrobromic acid, hydrochloric acid, hydroiodic acid, hydroxyethanesulfonic acid, lactic acid, maleic acid, malic acid, malonic acid, mandelic acid, methanesulfonic acid, mucic acid, naphthylanesulfonic acid, naphthylic acid, nicotinic acid, nitrous acid, oxalic acid, pelargonic, phosphoric acid, propionic acid, saccharin, salicylic acid, sorbic acid, succinic acid, sulfuric acid, tartaric acid, thiocyanic acid, thioglycolic acid, thiosulfuric acid, tosylic acid, undecylenic acid, and naturally and synthetically derived amino acids.

As used herein the term "preservative" refers to any known pharmaceutically acceptable preservative that functions by inhibiting bacteria, fungi, yeast, mold, other microbe, and/or by inhibiting oxidation. Suitable preservatives include but are not limited to antimicrobial agents and/or antioxidants. Suitable antimicrobial agents can include but are not limited to benzoates, benzyl alcohol, sodium benzoate, sorbates, propionates, and nitrites. Suitable antioxidants can include but are not limited to vitamin C, butylated hydroxytoluene (BHT), sulphites, and vitamin E.

The term "prevent," "preventing," or "prevention," as used herein refers to any reduction, no matter how slight, of a subject's predisposition or risk for developing a condition, disease, disorder or symptom thereof. For purposes of prevention, the subject is any subject, and preferably is a subject that is at risk for, or is predisposed to, developing a condition, disease, disorder. The term "prevention" includes either preventing the onset of a clinically evident condition, disease, disorder altogether or preventing the onset of a pre-clinically evident condition, disease, disorder in individuals at risk. This includes prophylactic treatment of subjects at risk of developing condition, disease, disorder.

As used herein, the term "solvent" refers to any pharmaceutically acceptable medium which is a liquid at ambient temperature, in which one or more solutes can be dissolved, or one or more substances can be partially dissolved or suspended, which medium is present in a provided composition in an amount of about 10 wt % or more. Numerous solvents are well known in the chemical and pharmaceutical arts and are contemplated herein and below.

As used herein, the term "solubilizing agent" refers to any pharmaceutically acceptable liquid medium, surfactant, and/or emulsifier that is present in a provided composition in an amount of less than about 10 wt %. One of skill in the chemical and pharmaceutical arts will readily appreciate that certain of the above-described solvents may also be used in substantially lower amounts such that they are characterized herein as solubilizing agents rather than solvents. Accordingly, in some embodiments, a solubilizing agent is any one of the above-listed solvents present in a provided formulation in an amount less than 10 wt % of the formulation. For example, in some embodiments, a solubilizing agent is a dialkylene glycol monoalkyl ether, such as, e.g., diethylene glycol monoethyl ether, present in an amount of less than 10 wt %. In some embodiments, a solubilizing agent is an alcohol, for instance, ethanol, present in an amount less than 10 wt %. Exemplary other such solubilizing agents are described below and herein.

The phrase "substantially pure" as used herein refers to an individual compound form, which is substantially devoid of all other forms, as well as degradation products of a form, and any residual solvent, and is at least 85% pure on a % weight basis, unless otherwise specified. The compound form can have at least 90% purity on a % weight basis, at least 93% purity on a % weight basis, at least 95% purity on a % weight basis, or at least 97%, 98%, 99%, or 99.5% purity on a % weight basis.

As used herein, "subject" or "individual" or "animal" or "patient" or "mammal," refers to any subject, particularly a mammalian subject, for whom diagnosis, prognosis, or therapy is desired, for example, a human.

As used herein, the term "superficial fungal infection of the skin" refers to a fungal infection present on the outer layer of skin, including *Tinea cruris* (jock itch), *Tinea corporis* (ringworm), *Tinea pedis*, interdigital *Tinea pedis*, moccasin-type *Tinea pedis, Tinea manuum, Tinea versicolor* (piyriasis), *Tinea nigra*, cutaneous candidiasis, *Tinea faciei* (facial ringworm), and white and black piedra. *Tinea corporis* (body ringworm), *Tinea cruris* (jock itch), and *Tinea faciei* (facial ringworm), can be caused by *Epidermophyton floccosum, Microsporum canis, Trichophyton mentagrophytes, T. rubrum, T. tonsurans, T. verrucosum*, and/or *T. violaceum. Tinea pedis* (athlete's foot) or *Tinea manuum* (fungal infection of the hand), are caused by *Epidermophyton floccosum, Microsporum canis, Trichophyton mentagrophytes, T. rubrum, T. tonsurans, T. verrucosum*, and/or *T. violaceum*. Cutaneous candidiasis can be caused by *C. albicans*.

As used herein, a "treatment" or "treating" of a disease, disorder, or condition encompasses alleviation of at least one symptom thereof, a reduction in the severity thereof, or the delay or inhibition of the progression thereof. Treatment need not mean that the disease, disorder, or condition is totally cured. A useful composition herein needs only to reduce the

severity of a disease, disorder, or condition, reduce the severity of symptoms associated therewith, provide improvement to a patient or subject's quality of life, or delay or inhibit the onset of a disease, disorder, or condition.

As used herein, all percentages are by weight of the total composition (i.e., wt %), unless otherwise specified.

Any concentration ranges, percentage range, or ratio range recited herein are to be understood as expressly disclosing and including any concentrations, percentages or ratios of any integer within that range and fractions thereof, such as one tenth and one hundredth of an integer, and any sub-range falling within a range, unless otherwise indicated.

Any number range recited herein relating to any physical feature, including for example, polymer subunits, size or thickness, are to be understood as expressly disclosing and including any integer or fraction of an integer within a disclosed range, or any sub-range within a disclosed range, unless otherwise indicated.

For the purpose of clarity, any element or feature of any method or composition or process described herein, can be combined with any other element or feature of any other method or composition or process described herein.

Other terms as used herein are meant to be defined by their well-known meanings in the art.

Solvents

As defined above, a gel composition of the present invention comprises one or more solvents as described above and defined herein. For instance, in some embodiments, a provided gel composition comprises only one solvent, such as a glycol solvent (e.g., propylene glycol) or an alkyl alcohol solvent (e.g., ethanol). In other embodiments, a gel composition of the present invention comprises more than one solvent. In some embodiments wherein a gel composition of the present invention comprises more than one solvent, the present invention refers to one of the more than one solvents as a "first solvent" and another of the more than one solvents as a "second solvent." In such instances, by "first solvent" is meant any of the solvents described above and herein; by "second solvent" is meant any of the solvents described above and herein other than the "first solvent." Likewise, also contemplated herein are additional solvents, e.g., a "third solvent," a "fourth solvent," etc., which solvents are also characterized in that each is a different solvent from the others. In some embodiments, a first or second solvent is, for example, a glycol solvent. In some embodiments, a first or second solvent is, for example, an alcohol solvent. Exemplary such one or more solvents, and combinations thereof, are contemplated by the present invention and described herein.

In some embodiments, a solvent is an alcohol solvent. In certain embodiments, the alcohol solvent is an alkyl alcohol. Exemplary such alcohol solvents include, but are not limited to, one or more of methanol, ethanol, n-propyl alcohol, isopropyl alcohol, n-butyl alcohol, t-butyl alcohol, 2-butanol, iso-butanol, pentanol, hexanol, cyclohexanol, and hexadecan-1-ol. In some embodiments, the alcohol solvent is methanol, ethanol, n-propyl alcohol, or isopropyl alcohol. In certain embodiments, the alcohol solvent is ethanol. In some embodiments, a solvent is a mixture of one or more such alcohols.

As used herein and unless otherwise indicated, the term "ethanol" refers to 190 proof USP grade ethanol. In some embodiments, USP grade ethanol is ethanol containing NLT 92.3% and NMT 93.8%, by weight, corresponding to NLT 94.9% and NMT 96.0%, by volume, at 15.56°, of C_2H_5OH.

In some embodiments, a solvent is, e.g., a triacetin and/or diol and/or polyol solvent. Diol solvents can include, but are not limited to, glycol solvents. In certain embodiments, a solvent is an alkylene glycol solvent. For instance, in some embodiments, the alkylene glycol solvent is ethylene glycol, propylene glycol, butylene glycol, or the like. In certain embodiments, the glycol solvent is propylene glycol.

In some embodiments, a solvent is a glycol ether. For instance, in some embodiments, a solvent is a dialkylene glycol monoalkyl ether, such as, e.g., diethylene glycol monoethyl ether. Other such glycol ethers are known in the chemical and pharmaceutical arts and are contemplated by the present invention.

In some embodiments, a solvent is present in a gel composition in an amount greater than 10 wt % to about 50 wt %; from greater than 10 wt % to about 45 wt %; from greater than 10 wt % to about 35 wt %; from greater than 10 wt % to about 30 wt %; from greater than 10 wt % to about 25 wt %; from greater than 10 wt % to about 20 wt %; from greater than 10 wt % to about 15 wt %; from about 15 wt % to about 30 wt %; from about 15 wt % to about 25 wt %; from about 15 wt % to about 20 wt %; from about 20 wt % to about 45 wt %; from about 25 wt % to about 45 wt %; from about 30 wt % to about 40 wt %; from about 16 wt % to about 24 wt %; from about 17 wt % to about 23 wt %; from about 18 wt % to about 24 wt %; from about 18 wt % to about 23 wt %; from about 18 wt % to about 22 wt %; from about 18 wt % to about 21 wt %; from about 18 wt % to about 20 wt %; from about 18.5 wt % to about 19.5 wt %; from about 19 wt % to about 20 wt %; from about 19 wt % to about 21 wt %; from about 19 wt % to about 22 wt %; from about 19 wt % to about 23 wt %; from about 19 wt % to about 24 wt %; from about 19 wt % to about 25 wt %; about 11 wt %; about 12 wt %; about 13 wt %; about 14 wt %; about 15 wt %; about 16 wt %; about 17 wt %; about 18 wt %; about 19 wt %; about 20 wt %; about 21 wt %; about 22 wt %; about 23 wt %; about 24 wt %; about 25 wt %; about 26 wt %; about 27 wt %; about 28 wt %; about 29 wt %; about 30 wt %; about 31 wt %; about 32 wt %; about 33 wt %; about 34 wt %; about 35 wt %; about 36 wt %; about 37 wt %; about 38 wt %; about 39 wt %; about 40 wt %; about 41 wt %; about 42 wt %; about 43 wt %; about 44 wt %; or about 45 wt %.

In some embodiments, a solvent is present in a gel composition in an amount of from about 16 wt % to about 24 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 17 wt % to about 23 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 18 wt % to about 22 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 18 wt % to about 21 wt %. In certain embodiments, a solvent is present in a gel composition in an amount of about 18 wt %. In certain embodiments, a solvent is present in a gel composition in an amount of about 19 wt %. In certain embodiments, a solvent is present in a gel composition in an amount of about 20 wt %.

In some embodiments, a solvent is present in a gel composition in an amount of from about 20 wt % to about 45 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 25 wt % to about 45 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 30 wt % to about 45 wt %. In some embodiments, a solvent is present in a gel composition in an amount of from about 35 wt % to about 45 wt %. In some embodiments, a solvent is present in a gel composition in an amount of about 35 wt %; about 36 wt %; about 37 wt %; about 38 wt %; about 39 wt %; about 40 wt %; about 41 wt %; about 42 wt %; about 43 wt %; about 44 wt %; or about 45 wt %. In certain embodiments, a solvent is present in a gel composition in an amount of about 41%.

In certain embodiments, a gel composition of the present invention comprises more than one solvent, wherein at least one of the more than one solvents is a glycol solvent.

In certain embodiments, a gel composition of the present invention comprises more than one solvent, wherein at least one of the more than one solvents is an alcohol solvent.

In certain embodiments, a gel composition of the present invention comprises more than one solvent, wherein at least one of the more than one solvents is an alcohol solvent and one of the more than one solvents is a glycol solvent. In certain embodiments, an alcohol solvent and a glycol solvent are each present in an amount of about 15 wt % to about 35 wt %. In certain embodiments, an alcohol solvent and a glycol solvent are each present in an amount of about 15 wt % to about 30 wt %. In certain embodiments, an alcohol solvent and a glycol solvent are each present in an amount of about 15 wt % to about 25 wt %. In certain embodiments, an alcohol solvent and a glycol solvent are each present in an amount of about 18 wt % to about 21 wt %. In some embodiments, the alcohol solvent is an alkyl alcohol (e.g., ethanol) present in an amount of about 15-25 wt % and the glycol solvent is an alkylene glycol (e.g., propylene glycol) present in an amount of about 15-25 wt %. In some embodiments, the alcohol solvent is ethanol and is present in an amount of about 18-20 wt % and the glycol solvent is propylene glycol and is present in an amount of about 18-20 wt %.

Solubilizing Agent:

In some embodiments, a gel composition of the present invention comprises one or more solubilizing agents as described above and defined herein. For instance, in some embodiments, the one or more solubilizing agent is a polysorbate solubilizing agent. In some embodiments, the one or more solubilizing agent is an alcohol solubilizing agent. In some embodiments, the one or more solubilizing agent is a dialkylene glycol monoalkyl ether solubilizing agent. Exemplary solubilizing agents are described below and herein.

In some embodiments, a solubilizing agent is a suitable surfactant or emulsifier. Suitable surfactants or emulsifiers include one or more non-ionic surfactants, PEG-80 sorbitan laurate (2,3-dihydroxypropyl octanoate) (e.g., TWEEN 28), a polyoxyethylene co-solvent, and polysorbate surfactants/emulsifiers.

In some embodiments, a solubilizing agent is a suitable surfactant. In certain embodiments, a suitable surfactant is a polysorbate. Exemplary polysorbate solubilizing agents include, but are not limited to, Polysorbate 20 (polyoxyethylen-(20)-sorbitanmonolaurate), Polysorbate 21 (polyoxyethylen-(4)-sorbitanmonolaurate), Polysorbate 25, Polysorbate 40 (polyoxyethylen-(20)-sorbitanmonopalmitate), Polysorbate 41, Polysorbate 45, Polysorbate 60 (polyoxyethylen-(20)-sorbitanmonostearate), Polysorbate 61 (polyoxyethylen-(4)-sorbitanmonostearate), Polysorbate 65 (polyoxyethylen-(20)-sorbitantristearate), Polysorbate 80 (polyoxyethylen-(20)-sorbitanmonooleate), Polysorbate 81 (polyoxyethylen-(5)-sorbitanmonooleate), Polysorbate 85 (polyoxyethylen-(20)-sorbitantrioleate), Polysorbate 120 (polyoxyethylen-(20)-sorbitanmonoisostearate), Polysorbate 121, and Polysorbate 125.

In certain embodiments, the polysorbate solubilizing agent is Polysorbate 20 (polyoxyethylen-(20)-sorbitanmonolaurate), Polysorbate 40 (polyoxyethylen-(20)-sorbitanmonopalmitate), Polysorbate 60 (polyoxyethylen-(20)-sorbitanmonostearate), Polysorbate 65 (polyoxyethylen-(20)-sorbitantristearate), or Polysorbate 80 (polyoxyethylen-(20)-sorbitanmonooleate).

In certain embodiments, the polysorbate solubilizing agent is Polysorbate 20 (polyoxyethylen-(20)-sorbitanmonolaurate). In certain embodiments, the polysorbate solubilizing agent is Polysorbate 80 (polyoxyethylen-(20)-sorbitanmonooleate).

In some embodiments, a solubilizing agent is a glycol ether. In some embodiments, asolubilizing agent is a dialkylene glycol monoalkyl ether. In certain embodiments, a solubilizingsolubilizing agent is diethylene glycol monoethyl ether. In some embodiments, a solubilizing agent is a glycol ether present in an amount of less than about 8 wt %. In some embodiments, a solubilizing agent is a glycol ether present in an amount of less than about 7 wt %. In some embodiments, a solubilizing agent is a glycol ether present in an amount of less than about 6 wt %. In some embodiments, a solubilizing agent is a glycol ether present in an amount of less than about 5 wt %. In some embodiments, a solubilizingsolubilizing agent is a glycol ether, e.g., diethylene glycol monoethyl ether, present in an amount ranging from about 0.5 wt % to about 3.0 wt %.

In some embodiments, it is highly desirable that a provided gel composition elicit reduced irritation, for example, reduced burning and/or stinging, in a subject, for example, as compared to the irritation elicited by known topical pharmaceutical compositions. Accordingly, in some embodiments, the presently described gel compositions do not comprise an alcohol solvent. Rather, in certain embodiments, a gel composition of the present invention comprises alcohol in a reduced amount, for instance as a solubilizing agent. In certain embodiments, a gel composition of the present invention comprises one or more solubilizing agents, wherein at least one solubilizingsolubilizing agent is a polysorbate solubilizing agent and at least one solubilizing agent is an alcohol solubilizing agent. In certain embodiments, a gel composition of the present invention comprises one or more solubilizing agents, wherein at least one solubilizingsolubilizing agent is a polysorbate solubilizing agent and at least one solubilizing agent is a dialkylene glycol monoalkyl ether solubilizing agent. In some embodiments, a gel composition of the present invention comprises a polysorbate solubilizing agent, an alcohol solubilizing agent, and optionally a third solubilizing agent. For instance, in certain embodiments, a gel composition of the present invention comprises a polysorbate solubilizing agent (e.g., Polysorbate 20), an alcohol solubilizing agent (e.g., an alkyl alcohol solvent such as ethanol), and a dialkylene glycol monoalkyl ether solubilizing agent (e.g., diethylene glycol monoethyl ether). Exemplary other such one or more solubilizing agents, and combinations thereof, are contemplated by the present invention and are described herein.

In some embodiments, the solubilizingsolubilizing agent is present in an amount of about 0.5 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 0.75 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 1.0 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 1.25 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 1.5 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 1.75 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 2.0 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 2.25 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 2.5 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 2.75 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 3.0 wt %. In some embodiments, a solubi-

lizingsolubilizing agent is present in an amount of about 3.25 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 3.5 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 3.75 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 4.0 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 4.25 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 4.5 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 4.75 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 5.0 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 6.0 wt %. In some embodiments, a solubilizingsolubilizing agent is present in an amount of about 7.0 wt %. In some embodiments, a solubilizing agent is present in an amount of about 8.0 wt %. In some embodiments, a solubilizing agent is present in an amount of about 9.0 wt %. In some embodiments, a solubilizing agent is present in an amount of less than about 10.0 wt %.

In some embodiments, a solubilizing agent is present in an amount ranging from about 0.5 wt % to about 3.0 wt %. In some embodiments, a solubilizing agent is present in an amount ranging from about 1.0 wt % to about 2.0 wt %. In some embodiments, a solubilizing agent is present in an amount of about 1.5 wt %.

In some embodiments, a solubilizing agent is present in an amount ranging from about 4.0 wt % to about 9.0 wt %. In some embodiments a solubilizing agent is present in an amount ranging from about 4.5 wt % to about 9.0 wt %. In some embodiments, a solubilizing agent is present in an amount ranging from about 5.0 wt % to about 9.0 wt %. In some embodiments, a solubilizing agent is present in an amount of about 5.0 wt %. In some embodiments, a solubilizing agent is present in an amount of about 8.0 wt %. In certain embodiments, a solubilizing agent is an alcohol solubilizing agent, e.g., ethanol, and is present in an amount of about 8.0 wt %.

Non-Carbomer Rheology Moder:

The non-carbomer rheology modifier for use in the presently described gel compositions can include any known rheology modifier/thickener that is not a carbomer.

In some embodiments, the non-carbomer rheology modifier for use in the presently described gel compositions can include any known rheology modifier/thickener that is not an alkyl cellulose, e.g., ethyl cellulose.

Suitable non-carbomer rheology modifiers/thickeners include hydroxy celluloses, semi-synthetic polymers including but not limited to carboxymethyl cellulose and starch; natural polysaccharides including but not limited to guar gum, locust bean gum, xanthan, chitosan and alginate. Suitable hydroxy celluloses hydroxyethyl cellulose (HEC), hydroxymethyl cellulose (HMC), hydroxypropyl cellulose (HPC), hydroxyethylmethyl cellulose (HEMC), and hydroxypropylmethyl cellulose (HPMC).

In some embodiments, the non-carbomer rheology modifier is hydroxyethyl cellulose (HEC) and is present in a described gel composition in an amount ranging from about 1.5 wt % to about 2.0 wt %. In certain embodiments, the hydroxyethylcelluose is present in an amount of about 1.75 wt %.

One of skill in the relevant chemical and pharmaceutical arts will appreciate that hydroxycelluloses are available in a variety of chain lengths and that the amount required by a particular formulation may vary depending on, inter alia, the chain length of the selected hydroxycellulose. In some embodiments, the HEC has a viscosity of between 100 and 25000 mPa's. In certain embodiments, the HEC has a viscosity of between 1500-2500 mPa's.

The described non-carbomer rheology modifiers/thickeners can be present in the described gel compositions in an amount of from >0.5 wt % to about 4 wt %; from >0.5 wt % to about 3 wt %; from >0.5 wt % to about 2.5 wt %; from >0.5 wt % to about 2 wt %; from >0.5 wt % to about 2.25 wt %; from >0.5 wt % to about 2 wt %; from about 0.5 wt % to about 4 wt %; from about 0.5 wt % to about 3 wt %; from about 0.5 wt % to about 2.5 wt %; from about 0.5 wt % to about 2.25 wt %; from about 0.5 wt % to about 2 wt %; from about 0.7 wt % to about 4 wt %; from about 0.7 wt % to about 3 wt %; from about 0.7 wt % to about 2.5 wt %; from about 0.7 wt % to about 2.25 wt %; from about 0.7 wt % to about 2 wt %; from about 0.9 wt % to about 4 wt %; from about 0.9 wt % to about 3 wt %; from about 0.9 wt % to about 2.5 wt %; from about 0.9 wt % to about 2.25 wt %; from about 0.9 wt % to about 2 wt %; from about 1 wt % to about 4 wt %; from about 1 wt % to about 3.5 wt %; from about 1 wt % to about 3 wt %; from about 1 wt % to about 2.5 wt %; from about 1 wt % to about 2.25 wt %; from about 1.1 wt % to about 2.3 wt %; from about 1.3 wt % to about 2.3 wt %; from about 1.4 wt % to about 1.7 wt %; from about 1.4 wt % to about 1.8 wt %; from about 1.4 wt % to about 1.9 wt %; from about 1.4 wt % to about 2 wt %; from about 1.4 wt % to about 2.1 wt %; from about 1.4 wt % to about 2.2 wt %; from about 1.4 wt % to about 2.3 wt %; from about 1.5 wt % to about 1.8 wt %; from about 1.5 wt % to about 1.9 wt %; from about 1.5 wt % to about 2 wt %; from about 1.5 wt % to about 2.1 wt %; from about 1.5 wt % to about 2.2 wt %; from about 1.5 wt % to about 2.3 wt %; from about 1.6 wt % to about 1.8 wt %; from about 1.6 wt % to about 1.9 wt %; from about 1.6 wt % to about 2 wt %; from about 1.6 wt % to about 2.1 wt %; from about 1.6 wt % to about 2.2 wt %; from about 1.6 wt % to about 2.3 wt %; from about 1.65 wt % to about 1.75 wt %; from about 1.65 wt % to about 1.85 wt %; from about 1.7 wt % to about 1.8 wt %; from about 1.7 wt % to about 1.9 wt %; from about 1.7 wt % to about 2 wt %; from about 1.7 wt % to about 2.1 wt %; from about 1.7 wt % to about 2.2 wt %; from about 1.7 wt % to about 2.3 wt %; from about 1.7 wt % to about 2.25 wt %; about 1.7 wt %; or about 1.75 wt % non-carbomer rheology modifier.

Preservatives:

The preservatives for use in the presently described gel compositions can include those described herein, including any known pharmaceutically acceptable preservative that functions by inhibiting bacteria and/or fungi, and/or by inhibiting oxidation. Suitable preservatives can include but are not limited to antimicrobial agents and/or antioxidants. Suitable antimicrobial agents can include but are not limited to benzoates, benzyl alcohol, sodium benzoate, sorbates, propionates, and nitrites. Suitable antioxidants can include but are not limited to vitamin C, butylated hydroxytoluene (BHT), sulphites, and vitamin E, as well as any known pharmaceutically acceptable preservative. In certain embodiments, the preservative is benzyl alcohol.

The described preservatives and/or antioxidants can be present in the described gel compositions in an amount of, for example, from about 0.001 wt % to about 15 wt %; from about 0.01 wt % to about 5 wt %; from about 0.2 wt % to about 4 wt %; from about 0.3 wt % to about 4 wt %; from about 0.4 wt % to about 4 wt %; from about 0.5 wt % to about 4 wt %; from about 0.6 wt % to about 4 wt %; from about 0.7 wt % to about 3 wt %; from about 0.8 wt % to about 2 wt %; from about 0.9